No. 80-680

Supreme Court, U. S.
FILED
OCT 27 1980
MICHAEL RODAK, JR., CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1980

JACK WERNER,

Petitioner,

v.

THE UPJOHN COMPANY, INC. AND
RALPH J. CARBO, JR., M.D.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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October 27, 1980

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QUESTIONS PRESENTED

1. Did the Fourth Circuit err in deciding the following questions so as to create a conflict with other federal appellate circuit decisions:

A. Does Federal Rules Evid. Rule 407, which provides that evidence of subsequent remedial measures "is not admissible" where its only purpose is to prove "negligence or culpable conduct," permit evidence of such measures in support of a strict liability claim in a products liability case?

B. Does Rule 407 permit evidence of subsequent remedial measures to prove negligence where the measures are not the result of unilateral action voluntarily taken by the manufacturer but are the result of pressure from the Food and Drug Administration, which is vested with legal authority to mandate the measures taken?

C. Does the provision of Rule 407 that "This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose [than to prove negligence or culpable conduct], such as proving ownership, control, or feasibility or precautionary measures, if controverted . . ." permit evidence of subsequent remedial measures to prove proximate causation where that issue is contested?

D. Is "feasibility" controverted within Rule 407, permitting evidence of subsequent remedial measures to show feasibility, if controverted, where the manufacturer defends its failure to warn that its drug should not be used for minor or trivial infections on the ground that "we believe that there is no precise definition of minor or trivial infections and the physician is adequately guided by the limitations of the approved INDICATIONS. Such a statement has the potential for much harm and little or no benefit"?

E. Where the trial court instructs the jury when evidence of subsequent remedial measures is admitted, and also in his final instructions, that those measures are, "not to be considered evidence to prove negligence or culpable conduct" on the part of the

manufacturer, is a specific, reasonably contemporaneous objection required for reversal at the instance of the manufacturer where the plaintiff's counsel makes an allegedly improper jury argument which the manufacturer contends urges the subsequent measures as proof of negligence?

F. What is the proper scope of review, and how much deference to trial court discretion should be given by the Courts of Appeals in the interpretation and administration of Rule 407, in relation to the scope of the exceptions to the rule, the adequacy of cautionary instructions, protection against prejudice, and whether error in application of the rule is "harmless"?

2. Does the provision of Rule 407 that "This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose [than to prove negligence or culpable conduct], such as proving ownership, control, or feasibility of precautionary measures, if controverted . . ." permit evidence of subsequent remedial measures to prove breach of express warranty?

3. Where expert witnesses testify that the instructions issued by a drug company with respect to a prescription drug are inadequate, in light of scientific knowledge at the time of issuance, for failure to give proper warning of side effects and proper description of the limited circumstances in which the use of the drug is indicated, does Rule 407 permit the experts to refer to the manufacturer's subsequently issued instructions as an example of the kind of instruction the manufacturer could have, and in the experts' opinion, should have given at the time plaintiff made his purchase?

4. Did the Fourth Circuit err in holding that a verdict in favor of defendant manufacturer on an issue submitted to the jury with regard to a strict liability claim is necessarily inconsistent with a verdict against the manufacturer on a negligence claim arising out of the same transaction?

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Summary

The Fourth Circuit Decision Is In Conflict With The Decisions Of Other Federal Courts Of Appeal On The Applicability, Scope, Interpretation And Administration Of Rule 407 Of The Federal Rules Of Evidence. The Conflicts Relate To Significant And Recurring Problems On Which Action By This Court Is Now Necessary To Achieve The Uniformity Which It Was The Declared Purpose Of The Federal Rules Of Evidence To Accomplish. In Addition, The Fourth Circuit Has Erroneously Decided Other Questions Relating To Rule 407, Involving Important Matters Of Federal Law And Policy Which Should Be Settled By This Court 12

Argument

I. The Fourth Circuit decision is in conflict with the decisions of other Federal Courts of Appeals on the following issues with respect to applicability, scope, interpretation and administration of Rule 407: (A) the applicability of Rule 407 to subsequent remedial measures in products liability cases involv-

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ing claims of strict liability; (B) the applicability of Rule 407 to subsequent remedial measures taken as a result of pressure by government regulatory authorities vested by law with coercive power to mandate the measures taken; (C) the effect of Rule 407 on the admissibility of subsequent remedial measures on issues of causation; (D) the meaning of "feasibility" in the provision of Rule 407 that states that evidence of subsequent remedial measures is admissible to prove "feasibility of precautionary measures, if controverted." (E) the necessity for specific, reasonably contemporaneous objection where evidence of subsequent remedial measures, properly in the case on some issues, is argued to the jury, allegedly improperly on other issues; and (F) the extent of the deference due to trial court discretion in the administration of Rule 407 12

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remedial measures to prove breach of express warranty and (B) the meaning of the provision of Rule 407 that where the Rule applies "evidence of . . . subsequent measures is not admissible to prove negligence or culpable conduct in connection with the event" 23

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OPINION BELOW

The opinion below is not yet reported. A copy is annexed in "Appendix A."

GROUNDS ON WHICH JURISDICTION OF THIS COURT IS INVOKED

(i) The date of the judgment sought to be reviewed, and the date of its entry, was August 4, 1980.

(ii) There has been no petition or order respecting a rehearing, and no order granting an extension of time within which to petition for certiorari.

(iii) Jurisdiction is conferred upon this Court by 28 U.S.C. §§ 1254(1) and 2101(c) to review the judgment in question by writ of certiorari.

STATUTE INVOLVED

Federal Rules of Evidence, Rule 407, as enacted by Pub. L. 93-595, 88 Stat. 1932:

> "Rule 407. Subsequent Remedial Measures
>
> When, after an event, measures are taken which, if taken previously, would have made the event less likely to occur, evidence of the subsequent measures is not admissible to prove negligence or culpable conduct in connection with the event. This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment."

STATEMENT OF THE CASE

This is a suit to recover damages for injuries due to the side effects of a prescription drug, (Clindamycin HCl) manufactured and marketed by respondent Upjohn, under the trade name "Cleocin," prescribed by the other respondent Dr. Carbo, an ophthalmologist, and taken by petitioner, Jack Werner. Federal jurisdiction in the court of first instance (The United States District Court for the District of Maryland) was based on diversity of citizenship and the requisite amount in controversy.

The complaint against Upjohn was for strict liability, breach of warranty and negligence, and the claim against Carbo was for negligence. After a nine-day trial, the jury, on issues, found both breach of warranty and negligence on the part of Upjohn, negligence on the part of Carbo, and damages of $400,000. From judgment entered on the verdict, Upjohn and Dr. Carbo appealed to the Fourth Circuit on numerous grounds, and Mr. Werner cross appealed from the trial court's direction of a verdict in favor of Upjohn as to punitive damages.[1]

The Fourth Circuit vacated the judgment and remanded for a new trial as to both respondents because the trial court "erred in admitting" into evidence a "package insert" issued by Upjohn at the behest of the Food and Drug Administration approximately two months after Mr. Werner's first illness from the drug.[2] With only one exception, the Court did not pass on any of the other questions presented by the appeal and cross appeal "since the case must be tried again and the questions now before us may not come up in a new trial or be presented in a different form upon somewhat different facts." (Appendix A. p. 20a).

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[1] The opinion below says "[P]laintiff filed a cross appeal arguing that the trial court erred in refusing to allow the plaintiff to present evidence on punitive damages." (Appendix A, p. 2a). This characterization of the ground of the cross appeal is simply incorrect.

[2] Package inserts are printed information accompanying each package of a drug shipped by the manufacturer to the pharmacist. The prescribing physician does not see the package insert, but receives printed material with the same text through other promotional channels, particularly so-called "Dear Doctor" letters addressed to every doctor. One of Upjohn's drug salesmen or "detail men" for Maryland, Richard Chatelaine, Jr., testified that only 50% of the doctors actually read the "Dear Doctor" letters mailed to them.

The drug, a broad spectrum, systemic antibiotic, was prescribed and taken in capsule form for a sty, a minor infection of the eyelid. The drug caused pseudomembranous colitis, an extremely severe form of colitis which in some cases caused death. As a result, some 5½ feet of Mr. Werner's colon had to be removed and several other operations on Mr. Werner's gastointestinal tract were required. Mr. Werner is seriously and permanently disabled.

The drug was prescribed for petitioner in December, 1974. By that time, Cleocin had been heavily promoted, and had become one of the top-selling drugs in Upjohn's catalogue. The then most recent package inserts and promotional material issued in August, 1974, described Cleocin as "indicated" in treatment of "skin and soft tissue infections" of susceptible strains of streptococci and staphylococci, and they specified dosages for "mild" as well as "moderately severe" and "severe" infections. Mr. Werner's condition was a mild, or minor, soft-tissue infection.[3] His prescription was for 600 mg. per day, and he took the drug for some four days. The package insert stated: "Doses up to 2 Gms. Cleocin . . . per day for 14 days have been well tolerated by healthy volunteers, except that the incidence of gastrointestinal side effect is greater with the higher doses."

Before August, 1974, Upjohn's own evaluation of cases involving "Terminal Event [death] and Cleocin Usage" (PX 60) showed six deaths "caused" by Cleocin colitis, 19 deaths from colitis "contributed to" by Cleocin and an

[3] The August 1974 package insert, like all previous inserts, also recommended Cleocin for respiratory infections. Of a total of 4.5 to 6 million prescriptions in 1973, over 2 million were for sore throats and upper respiratory infections, 80% of which are viral and not susceptible to Cleocin. Some 93,000 were for the common cold, as to which Cleocin is concededly totally ineffective.

additional 19 deaths from colitis as to which it was "questionable" whether Cleocin was "causal" or "contributory." By November, 1974, Upjohn had documented (PX 52, "Colitis Family Factual Outcomes") 59 Cleocin colitis-related deaths. Nevertheless, Upjohn's promotional material did not mention the possibility of death from colitis as a side-effect, although Upjohn's own expert, Dr. Frank Calia, professor at the University of Maryland Medical School specializing in infectious diseases, testified that failure to warn a patient of *any possible* "very severe and serious reaction" is a "very very serious failure."[4] Moreover, an Upjohn memorandum of a meeting with Food and Drug Administration representatives on July 29, 1974 reported that the FDA, which "had little adverse reaction data beyond that supplied by us," had information showing only nine fatal cases from any kind of Cleocin colitis through June, 1974; obviously Upjohn had reported to the FDA less than all the information it had about Cleocin colitis fatalities.

Indeed, as early as July, 1974, Upjohn instructed its detail men in writing to suspend active promotion of oral Cleocin and to promote only injected Cleocin and then only in hospitals and for serious infections. According to the chief of Upjohn's market planning for all Upjohn's prescription products, the reason was that that instruction "accurately described the environment in which the risk-benefit ratio for the product was logical;" Upjohn had learned that the risk of pseudomembranous colitis was four times as great from oral ingestion of Cleocin as from injections. Nevertheless, through October, 1974, Upjohn continued to pursue a vigorous advertising program in 22 medical journals (PX 53), promoting Cleocin for use "in

[4] Plaintiff's gastroenterologist, Dr. Axelrod, agreed that "an antibiotic that is considered to be a factor in causing death of a patient would call for a warning by the people who make the drug."

the office . . . in the hospital" for a large number of indications, including "skin and soft tissue infections" and praising the drug as "readily absorbed . . . widely distributed."

Upjohn's August, 1974, package insert and "Dear Doctor" letter not only omitted any warning of possibly fatal side effects of Cleocin, but also gave no information that Upjohn was aware that the "risk-benefit ratio for the product" called for Cleocin to be taken only in the hospital, only by injection, and only for serious infections. Instead, it promoted the use of Cleocin capsules for mild soft-tissue and respiratory infections.

The "Dear Doctor" letter transmitted a copy of the August, 1974 package insert; and, in an effort to persuade physicians to "continue to find that . . . Cleocin . . . [is] a useful and efficacious antibiotic . . ." stated as Upjohn's "best estimate" that "a serious colitis probably occurs at an overall rate of between one in 50,000 and one in 100,000 uses of clindamycin." These figures, as Upjohn's Group Research Manager in Medical Affairs conceded, do not reflect any of the medical studies sponsored by Upjohn itself, in all of which the rate of incidence was concededly much higher. One of plaintiff's experts characterized Upjohn's "best estimate" as a "gross underestimate" and another, who had made what Upjohn's president, testifying in the U.S. Senate hearings on Cleocin in 1975, called the "determinative" test for Cleocin colitis, found the estimate in the "Dear Doctor" letter "totally unacceptable."[5]

[5] This witness, Dr. Tedesco, had run extensive and careful tests for Upjohn, and found an incidence rate of 10% for pseudomembranous colitis, which he reported to Upjohn as early as 1973.

In November, 1974, Upjohn's vice president in charge of Domestic Pharmaceutical Marketing wrote to Upjohn's Directors and Sales Managers "to again emphasize, as we have been doing for some time, that Cleocin should only be recommended in the treatment of serious infections. Sales representatives should not discuss or recommend Cleocin in the treatment of trivial infections."

In March, 1975, under pressure by the FDA, a new package insert was substituted for the August, 1974 insert. That pressure grew so strong that Upjohn could no longer succeed in its strategy, which Upjohn's own representatives had described as being to "slow down this steamroller effect of removing all indications other than anaerobic effects for Cleocin products."

The new insert pointed out clearly in the first sentence of the "WARNING" at the very beginning of the insert that Cleocin "can cause severe colitis which may end fatally." The second sentence stated that "Therefore, it should be reserved for serious infections where less toxic antimicrobial agents are inappropriate . . ." The "Indications" no longer encouraged use for mild infections and instead called for limitation to *serious* infections, stating "Its use should be reserved for penicillin-allergic patients or other patients for whom, in the judgment of the physician a penicillin is inappropriate. Because of the risk of colitis, as described in the WARNING box, before selecting . . . [Cleocin] the physician should consider the nature of the infection and the suitability of less toxic alternatives (e.g., erythromycin)."

Upjohn asked, by way of pre-trial relief, that the trial court rule *in limine* that "no reference . . . be made in opening statements or the evidence to revisions by the Upjohn Company of the package insert or drug literature for Cleocin subsequent to December 10, 1974." The court denied the request. Mr. Werner's trial counsel offered the 1975 insert in evidence and Upjohn objected "for the reasons advanced at the preliminary hearing in this case," i.e., that under Fed. Rules Evid. Rule 407 the 1975 insert was not admissible for any purpose.

The trial court overruled the objection and at the time the evidence was admitted told the jury that the insert was "being admitted for a limited purpose; it is not to be considered by you in consideration of the evidence in the case as to the Defendant Carbo, and as to Defendant Upjohn it is not to be considered evidence to prove negligence or culpable conduct in connection with the case. I will give you in my instructions the limited effect you can give to this particular exhibit." Later, the court repeated to the jury that the evidence was not being admitted to prove negligence or culpable conduct and promised a full instruction at the end of the case as to how the evidence could be used.

In its instructions at the end of the case the trial court said: "The insert dated March, 1975 was also admitted into evidence, but, again, cannot be considered as to Dr. Carbo, and is admitted as to the Defendant Upjohn only to indicate the changes that were made between August, 1974, and March, 1975, and it is not to be considered as any evidence of any negligence of Upjohn; simply to indicate the feasibility of any precautionary measures that Plaintiff suggests should have been taken."

Upjohn did not concede feasibility. It contended that in 1974 it could not write a practical warning limiting the

use of Cleocin to serious infections, because "there is no precise definition of minor or trivial infections," and the use of such adjectives without definition creates "the distinct possibility of misleading."

Respondents reiterated their position as to the 1975 warning in their exceptions to the trial court's instructions: "The Defendant Upjohn excepts to the Court's instructions to the jury which permits them *in any way* to consider the 1975 package insert as evidence in the case *for any purpose whatsoever;* our position being that the 1975 insert should not be admitted in evidence in the first place, and having been admitted under what has come in, the jury should be instructed that they are to disregard the 1975 insert in making *any* finding on *any* of the issues that have been submitted to them by the Court." (Emphasis supplied).

The references to the 1975 insert during the trial were not by way of attempt to prove negligence or culpable conduct from the fact that the insert was issued, or from any inference that the subsequent warning amounted to an admission that the 1974 warning was negligent. The proof of negligence came from the experts, not from the later insert. There was ample explicit expert testimony that before December 1974, Upjohn knew that Cleocin should not have been prescribed except for life-threatening or sight-threatening conditions not otherwise treatable, because for any less serious condition, other antibiotics would be safer and at least as effective. Negligence as to the 1974 insert was directly proved by experts. Their references to the 1975 insert were illustrative and clarificatory — having testified that based on the knowledge Upjohn had in 1974, the 1974 warning was deficient in specified respects, they pointed to the 1975 excerpt as a specific example of the kind of wording that could have been written in 1974 to remedy the defects they had pointed out in their testimony.

The 1975 warning was also referred to in Dr. Carbo's testimony that if that warning had been extant in 1974 he would never have prescribed Cleocin for the plaintiff (App. 293-4). This testimony was corroborated by: (1) the other experts who agreed that if the 1975 warning had been issued in 1974 the "climate" or "outlook" of the profession in 1974 as to the prescription of Cleocin would have been entirely different; and (2) evidence that if a similar warning had been issued in 1974 even doctors who did not read their "Dear Doctor" letters directly would have been alerted by "something [that] would come across our desk and the different journals would have alerted us too;" (3) evidence that discussions with colleagues would have been an additional likely source to alert Dr. Carbo if a proper warning had been published; and (4) evidence that following the 1795 insert, there was a 71.5% drop in sales during 1975 and an even further decline in 1976.

Plaintiff's trial counsel referred to the 1975 insert in his closing argument in the following passage quoted in the opinion below:

> "If we were to boil this down to the least common denominator, if you were to be asked tomorrow, after, hopefully, the case is decided and done with, what was the biggest single thing that Upjohn did wrong that impells [sic] you to bring in a verdict for the plaintiff against Upjohn, would you not have to say Upjohn knew of the fatalities and didn't tell the doctors until much later, after this whole episode was over and done? That they knew it should not be used for other than serious, life-threatening infections? That they knew there were other less toxic antibiotics which were appropriate, and they told people that later? That they knew that they had, according to their people, cut off promotion of the drug in the middle of '74, but didn't tell the doctors that? Don't you think, honestly, and you have to answer this to yourselves, don't you think any one of those four things was a violation of a duty which any ethical

> drug manufacturer owes the public, to keep the public informed, or keep the doctors informed so the public can be informed?
>
> Instead of that, they held it under their belt; they continued the advertising for at least four more months, in many instances. They held off the change until March of '75; [the date the 1975 warning was released] nine months after they knew this, and they cashed in as much as they could.
>
> * * * * * *
>
> But, in this delay, from July 1 to March of '75, before they really cut and told the doctors what they should have told them long ago, in that nine month period, . . ."

Upjohn did not object to this argument. The Fourth Circuit held that the argument was "sufficiently out of bounds" to "excuse the contemporaneous objection requirement," because "the clear impact of this argument" was "that Upjohn breached its duty of due care by failing to adopt the 1975 warning in 1974," and [t]hus, plaintiff used the substance of the subsequent warning to prove antecedent negligence and thereby violated Rule 407."

The Fourth Circuit "as an alternate ground for a new trial for Upjohn," also held "that the verdict for Upjohn on the issue of strict liability is inconsistent with the verdict against Upjohn on the issue of negligence" because "the effect of the jury verdict on negligence was to find that Upjohn failed to use due care to give an adequate warning of the propensities of the drug marketed, and in the same breath, the verdict on strict liability found that the drug marketed with such an inadequate warning was not unreasonably dangerous." However, as the trial court instructed the jury, a manufacturer is strictly liable only where the defect in the product exists at the time the product leaves the manufacturer's control, and the jury could have found that Upjohn's negligence was in failing

to get the relevant information to physicians through detail men and other channels *after* the particular Cleocin taken by plaintiff had left its hands.[6]

REASONS FOR GRANTING THE WRIT

SUMMARY

THE FOURTH CIRCUIT DECISION IS IN CONFLICT WITH THE DECISIONS OF OTHER FEDERAL COURTS OF APPEALS ON THE APPLICABILITY, SCOPE, INTERPRETATION AND ADMINISTRATION OF RULE 407 OF THE FEDERAL RULES OF EVIDENCE. THE CONFLICTS RELATE TO SIGNIFICANT AND RECURRING PROBLEMS ON WHICH ACTION BY THIS COURT IS NOW NECESSARY TO ACHIEVE THE UNIFORMITY WHICH IT WAS THE DECLARED PURPOSE OF THE FEDERAL RULES OF EVIDENCE TO ACCOMPLISH. IN ADDITION, THE FOURTH CIRCUIT HAS ERRONEOUSLY DECIDED OTHER QUESTIONS RELATING TO RULE 407, INVOLVING IMPORTANT MATTERS OF FEDERAL LAW AND POLICY WHICH SHOULD BE SETTLED BY THIS COURT.

ARGUMENT

I. THE FOURTH CIRCUIT DECISION IS IN CONFLICT WITH THE DECISIONS OF OTHER FEDERAL COURTS OF APPEALS ON THE FOLLOWING ISSUES WITH RESPECT TO APPLICABILITY, SCOPE, INTERPRETATION AND ADMINISTRATION OF RULE 407: (A) THE APPLICABILITY OF RULE 407 TO SUBSEQUENT REMEDIAL MEASURES IN PRODUCTS LIABILITY CASES INVOLVING CLAIMS OF STRICT LIABILITY; (B) THE APPLICABILITY OF RULE 407 TO SUBSEQUENT REMEDIAL MEASURES TAKEN AS A

[6] Note, "Proof, Under Strict Liability Doctrine That Defect Was Present When Product Left Hands of Defendant," 54 A.L.R.3d 1079 (1973). Another reason why the verdict is consistent is the form of the issues submitted to the jury, discussed in the argument, below, at page 27 n.11.

RESULT OF PRESSURE BY GOVERNMENT REGULATORY AUTHORITIES VESTED BY LAW WITH COERCIVE POWER TO MANDATE THE MEASURES TAKEN; (C) THE EFFECT OF RULE 407 ON THE ADMISSIBILITY OF SUBSEQUENT REMEDIAL MEASURES ON ISSUES OF CAUSATION; (D) THE MEANING OF "FEASIBILITY" IN THE PROVISION OF RULE 407 THAT STATES THAT EVIDENCE OF SUBSEQUENT REMEDIAL MEASURES IS ADMISSIBLE TO PROVE "FEASIBILITY OF PRECAUTIONARY MEASURES, IF CONTROVERTED;" (E) THE NECESSITY FOR SPECIFIC, REASONABLY CONTEMPORANEOUS OBJECTION WHERE EVIDENCE OF SUBSEQUENT REMEDIAL MEASURES, PROPERLY IN THE CASE ON SOME ISSUES, IS ARGUED TO THE JURY, ALLEGEDLY IMPROPERLY ON OTHER ISSUES; AND (F) THE EXTENT OF THE DEFERENCE DUE TO TRIAL COURT DISCRETION IN THE ADMINISTRATION OF RULE 407.

A. *The Fourth Circuit decision erroneously rejected other Federal appellate decisions in holding that Rule 407 excludes evidence of subsequent remedial measures on the issue of strict liability in a products liability case.*

The opinion below concedes that the Fourth Circuit decision in this case is contrary to the weight of authority, including other Federal Appellate authority. The opinion states:

> "Plaintiffs principal argument . . . [for nonapplicability of Rule 407] is that the 1975 warning is admissible because the suit involves a strict liability claim. The courts have split on this proposition. We suppose, without making a numerical comparison, that the majority of courts would admit the evidence for one reason or another. Compare, e.g., . . . *Robbins v. Farmers Union Grain Terminal Ass'n.*, 552 F.2d 788 (8th Cir. 1977) [holding evidence of subsequent warning admissible]" (Appendix A, p. 12a).

The Eighth Circuit has squarely held, contrary to the decision below, that evidence of a subsequent warning is admissible, notwithstanding Rule 407, in a products liability case involving a strict liability claim, where the claimed defect in the product is failure to give adequate warning of potential danger from use of the product as directed. *Robbins v. Farmers Union Grain Terminal Ass'n.*, 552 F.2d 788 (8th Cir. 1977) (pointing out at p. 793, n.9 that Rule 407 was closely patterned after Calif. Ev. Code § 1151, which was held in *Ault v. International Harvester Co.*, 13 Cal. 3d 113, 117 Cal. Reptr. 812, 528 P.2d 1148 (1975) not to preclude admission of subsequent remedial measures in strict liability cases); *Farner v. Paccar, Inc.*, 562 F.2d 518 (8th Cir. 1977). Weinstein's Evidence (1977) § 407[03] comments with approval on the thoroughness of the discussion in *Robbins, supra.* The Seventh Circuit, in 1974, discussing Rule 407 as then proposed (which was identical to the Rule as finally adopted, Weinstein's Evidence (1977) page 407-1) also reached the conclusion that Rule 407 does not exclude evidence of subsequent remedial measures offered on the issue of strict liability. *Lolie v. Ohio Brass Co.*, 502 F.2d 741, 744 (7th Cir., 1974).

The overwhelming weight of authority holds that rules like Rule 407 do not apply to claims of strict liability in products liability cases.[7] The reasons for the majority view are: (1) since fault is irrelevant in a strict liability case, the evidence is not offered to prove negligence or culpable conduct; and (2) the manufacturer of mass-produced products would not be deterred from making corrections by

[7] Note, "Admissibility of Evidence of Subsequent Repair or other Remedial Measures in Products Liability Cases," 74 A.L.R.3d 1001 (1976) at pages 1009, 1010 and Sections 6[a], 10, 13 and 15; Weinstein's Evidence (1977) § 407[03]; Dixon, Drug Products Liability (1976) § 9.09; Note, Products Liability, Subsequent Remedial Measures, Subsequent Design Changes Admissible in Strict Liability Suit, 44 U. Cin. L. Rev. 673 (1976) Note, Products Liability and Evidence of Subsequent Repairs,

admitting the evidence, since the risk of numerous further lawsuits if the defect is not corrected is much more threatening than the increase, by reason of making the correction, in the risk of liability in any one case in litigation. In fact, the policy of the doctrine of strict liability itself would be subverted by excluding the evidence. Exclusion would simply deprive the trier of fact of relevant evidence and thwart the purpose of consumer protection in a mass market, upon which the doctrine of strict liability is based, without any corresponding social benefit. To apply Rule 407 in a strict liability case would, as the Fifth Circuit put it, "turn the blade inward," *Rozier v. Ford Motor Co.*, 573 F.2d 1332 (5th Cir. 1978), rehearing denied 578 F.2d 871. It would use Rule 407 to reach a result "contrary to the public policy of encouraging the distributor of mass produced goods to market safer products," *Barry v. Manglass*, 55 A.D.2d 1, 389 N.Y.S.2d 870, 875 (1976).[8] The opinion below puts the question as being "whether the policy behind the common law rule [would] be served or subverted if evidence of subsequent precautionary measures be admitted to prove strict liability" (Appendix A, p. 13a). However, the common law rule, which, as the Fourth Circuit held, is codified in Rule 407, was fashioned before the rise of the modern doctrine of

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1972 Duke L.J. 837, 848-860; *Ault v. International Harvester Co.*, 13 Cal. 3d 113, 117 Cal. Reptr. 812, 528 P.2d 1148 (1975); *Love v. Wolf*, 249 Cal. App. 2d 822, 58 Cal. Reptr. 42 (1967); *Sutkowski v. Universal Marion Corp.*, 5 Ill. App. 2d 313, 281 N.E.2d 749 (1972); *Barry v. Manglass*, 55 A.D.2d 1, 389 N.Y.S.2d 870 (1976); *Ginnis v. Mapes Hotel Corp.*, 86 Nev. 408, 470 P.2d 135 (1970); *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206 (1971); *Chart v. General Motors*, 258 N.W.2d 680 (Wis., 1977).

[8] The law of Maryland, which governs as to matters of substance in this diversity action is contrary to Rule 407 on the procedural issue here involved: subsequent remedial measures are admissible to prove negligence in Maryland. *Blanco v. J.P. Penny*, 251 Md. 707, 248 A.2d 645 (1968).

strict liability for consumer products. In focusing solely on the policy of the common law rule of evidence, the opinion below fails to give proper weight to the public policy underlying strict liability. The heart of the opinion below on this point is the argument that although "strict liability . . . involves conduct . . . less blameworthy than simple negligence," "[f]rom a policy standpoint it follows that if the rule expressly excludes evidence of subsequent repairs to prove culpable conduct that the same should be true for strict liability." (Appendix A, p. 13a). This is a *non sequitur*.

The Fourth Circuit has held below that it makes a difference that the defect here is not inherent in the product but is due to failure to give adequate warning. This distinction is unsound, and is explicitly rejected by the Eighth Circuit and by the great majority of the cases which have considered the question. These cases correctly hold that "The article can have a degree of dangerousness because of a lack of warning which the law of strict liability will not tolerate even though the actions of the seller were entirely reasonable in selling the article without a warning considering what he knew or should have known at the time he sold it." *Robbins v. Farmers Union Grain Terminal Ass'n.*, 552 F.2d 788 (8th Cir. 1977). See also 2 Frumer and Friedman, Products Liability (1978) Section 16A[4][f][vi], pages 3B-140 through 3B-154 (distinction between negligence and strict liability where defect due to failure to warn is "quite significant"); *Jackson v. Coast Paint and Lacquer Co.*, 499 F.2d 809 (C.A. 9, 1974) (same theory of nature of strict liability in failure-to-warn cases as *Robbins*); *Berkebile v. Brantly Helicopter Corp.*, 462 Pa. 83, 337 A.2d 893 (1975) ("In the strict liability context we reject standards based on what the 'reasonable' manufacturer could be expected to 'foresee' about the consumers who use his product . . . Rather, the sole question here is whether the seller accompanied

his product with sufficient instructions and warnings to make his product safe"); *Ulrich v. Kasco Abrasives Co.*, 532 S.W.2d 197 (Ky., 1976); *Hamilton v. Hardy*, 549 P.2d 1099 (Colo. App., 1976), certiorari denied by Colorado Supreme Court) (trial court reversed for not giving strict liability instruction, in addition to negligence instruction, for failure to warn the medical profession, for the benefit of patients, of dangers of oral contraceptive; in strict liability claim jury should be instructed that the issue is whether the manufacturer's failure to give adequate warning rendered the product unreasonably dangerous, without regard to the reasonableness of the manufacturer's conduct in failing to warn when judged by negligence standards; manufacturer obligated under strict liability to give warning of facts possibly implicating product in dangerous side effects even if it reasonably believes that cause and effect relationship has not been definitively proved); *Phillips v. Kimwood Machine Co.*, 269 Or. 485, 525 P.2d 1033, 1039 (1974), (overruling *Anderson v. Klix Chemical Co.*, 256 Or. 199, 472 P.2d 806 (1970); good discussion). Cf. *Nolan v. Dillon*, 261 Md. 516, 523, 276 A.2d 36, 40 (1971), (Sparine warning would be adequate "even in jurisdictions which have espoused strict liability," indicating that standard of liability is stricter for strict liability than for negligence even where defect consists of failure to warn; case decided before Maryland adopted strict liability rule of Restatement of Torts, 2d, Section 402A).

B. *The Fourth Circuit decision erroneously rejected other Federal appellate decisions in holding that Rule 407 rendered evidence of subsequent remedial measures inadmisible even though they were taken under pressure from the Food and Drug Administration, which was vested with legal authority to mandate the action taken.*

The decision below is in conflict with other federal appellate authority which holds that where, as here,

subsequent remedial measures were taken as a result of pressure by government regulatory authority having coercive power, the exclusionary provisions of Rule 407 are inapplicable. *Rozier v. Ford Motor Co.*, 573 F.2d 1332, 1343 (5th Cir., 1978) ("Invoking . . . [Rule 407] to justify exclusion here is particularly inappropriate since the estimate was prepared not out of a sense of social responsibility but because the remedial measure was to be required in any event by a superior authority, the National Highway Traffic Safety Administration"); *Farner v. Paccar*, 562 F.2d 518 (8th Cir., 1977) (subsequent auto safety recall letter pursuant to Federal Motor Vehicle Safety Act of 1966); *Lolie v. Ohio Brass Co.*, 502 F.2d 741 (7th Cir., 1974) (direction of State Mine Inspector). See also, for pre-Rule 407 law to the same effect, *L. & N.R. Co. v. Williams*, 370 F.2d 839 (5th Cir., 1966).

The reason why Rule 407 does not apply is that where the remedial measures are not voluntary, the policy of the rule, namely to encourage voluntary safety measures, does not apply. *Barry v. Manglass*, 55 A.D.2d 1, 389 N.Y.S.2d 870 (1976).

The opinion below argues that because the FDA encourages drug manufacturers to issue stronger warnings without FDA approval, admitting subsequent warnings to prove negligence where the changes have been required by the FDA, would discourage unilateral changes by the manufacturers voluntarily made in the public interest (Appendix A, p.19a). This is a *non sequitur*.

C. *The Fourth Circuit erroneously rejected other Federal appellate decisions in holding that Rule 407 excludes evidence of subsequent remedial measures on the issue of causation.*

The opinion below holds "that the policy behind Rule 407 does not allow for a new exception to prove causation."

(Appendix A, p.17a). Causation, however, is not a "new" exception to Rule 407. The opinion below concedes that Rule 407 "merely enacts the common law rule" (Appendix A, p.13a) and that the list of exceptions in Rule 407 is "illustrative and not exhaustive" (Appendix A, p. 12a). As Judge Weinstein points out, Weinstein's Evidence (1977) p. 407-6, "Rule 407's second sentence continues the present practise in recognizing that the exclusionary rule is not applicable to the proof of a consequential, material fact in issue other than negligence. . . . The admission of subsequent remedial measures for such purposes is governed by the general requirements of relevancy under Rules 401 to 403."

The common law rule admitted evidence of subsequent remedial measures where relevant to the issue of causation. *Robbins v. Farmers Union Grain Terminal Ass'n.*, 552 F.2d 788, 794 (8th Cir., 1977) explicitly noted as an additional basis for admitting the evidence of subsequent warning in that case that "more relevant is the fact that a remedial [warning] instruction may provide substantial evidence that with a different instruction the harm would not have resulted (causation)."

The question of causation was sharply in issue in the case at bar. Upjohn argued that because Dr. Carbo did not read the 1974 warning, the failure to include in that warning the possibility of fatal side effects and the limitation of Cleocin to serious infections of penicillin-allergic patients was in no event the proximate cause of plaintiff's injury. The precise language of the 1975 package insert, and the evidence of the dramatic decline in sales after that particular warning were relevant to establish that the failure to warn was responsible for extensive overprescription, of which plaintiff was a victim, and was therefore in fact a proximate cause of plaintiff's injury; if the 1974 insert had given proper warning and instructions, plaintiff would probably never have received the drug.

There was also expert testimony that if the profession had had the 1975 warning in 1974, the climate or "outlook" as to the prescription of Cleocin would have been entirely different. Dr. Carbo testified that if proper warning had been given in 1974, he would never have prescribed Cleocin for plaintiff regardless of whether or not he had read the 1974 package insert and "Dear Doctor" letter. The only way to test that testimony was in light of "the specific . . . nature of the warning"[9] and the effect of that warning on actual sales. The subsequent warning is vital to give meaning to the 75% drop in sales which took place after the warning in spite of the fact that, as one of Upjohn's detail men for Maryland testified, 50% of the physicians do not read the "Dear Doctor" letters that contain drug warnings and instructions. Without the evidence of the subsequent warning, petitioner would have been seriously prejudiced on the hotly contested issue of whether Upjohn's failure to give proper warning was a proximate cause of petitioner's injuries in view of Dr. Carbo's failure to read the 1974 warning that was given.

D. *The Fourth Circuit erroneously rejected other Federal appellate decisions in holding that feasibility of remedial measures was not controverted in this case.*

The Fourth Circuit held below that feasibility was not controverted in this case. The opinion agreed that when the FDA first mentioned a package insert instructing that Cleocin should not be used for minor or trivial infections, Upjohn replied "[*We believe that*] *there is no precise definition of minor or trivial infections* and the physician is adequately guarded by the limitations of the approved INDICATIONS. Such a statement has the potential for much harm and little or no benefit" (Appendix A,

[9] The quotation is from the testimony of Joseph E. Heimonen, who was responsible for Upjohn's marketing planning for U.S. prescription drugs.

p. 10a, Emphasis supplied). The Fourth Circuit held, however, that this position "does not controvert the feasibility of writing a warning that Cleocin not be used for minor infections. It merely questions the necessity for such a warning . . . Upjohn does not argue that it could not have written a stronger warning, it argues that the 1974 warning was adequate given the knowledge it had at that time. This defense simply does not raise an issue of feasibility" (Appendix A, p. 10a).

The Fourth Circuit's interpretation of "feasibility" is unduly narrow. The term means more than "possibility;" it is to be interpreted, "in terms of cost, practicality and technological possibility." *Robbins v. Famers Union Grain Terminal Ass'n.*, 552 F.2d 788 (8th Cir., 1977). See Weinstein's Evidence (1977) pages 407-11, 407-14, 407-15. The position that there is no precise definition of minor infection goes to the practicality of giving the warning. Feasibility was not uncontroverted merely because advisability was controverted as well.

The line between "feasibility" and "negligence," may be "to a considerable extent arbitrary," Weinstein's Evidence § 407[02] page 407-11, but the opinion below draws the line much too strictly against "feasibility."

E. *The Fourth Circuit erroneously rejected other Federal appellate authority in holding that specific, reasonably contemporaneous objection was not required for reversal on the ground of allegedly improper jury argument from evidence of subsequent remedial measures.*

The opinion below holds that "to use evidence of subsequent remedial measures to argue negligence . . ." is reversible error even where there is no contemporaneous objection. If petitioner is correct that the evidence of the 1975 warning was admissible on one or more grounds other than negligence, the decision below also

conflicts on this point with *Robbins v. Farmers Union Grain Terminal Ass'n.*, 552 F.2d 788 (8th Cir., 1977), which specifically held that under those circumstances such an objection is necessary in order to preserve the question for appeal.

F. *The Fourth Circuit erroneously rejected other Federal appellate authority as to the deference due to trial court discretion in the administration of Rule 407.*

The decision below reflects an unduly constricting attitude toward trial court administration of Rule 407. The trial court is generally given "large discretion" in the administration of Rule 407 and should be reversed only for abuse of discretion, where it has determined that plaintiff's evidence is admissible under one of the exceptions to the rule, or that a limiting instruction is sufficient under the circumstances. Weinstein's Evidence § 407[05], pages 407-23 to 407-24. Thus, in *Farner v. Paccar*, 562 F.2d 518 (8th Cir., 1977) plaintiff in a motor vehicle collision case alleged strict liability, negligent design and negligent failure to warn. The jury found for defendant on strict liability and for plaintiff on negligence. Judgment for plaintiff was affirmed against defendant's contention that the trial court erred in admitting a subsequent recall notice. The Eighth Circuit held that the recall notice was admissible on the strict liability claim, and was fully in the case because there was no request for a limiting instruction. The court pointed out that even if there had been error, it was not prejudicial because there was independent evidence of design defect; and in any event, the weighing of any possibly prejudicial effect of evidence of subsequent measures is a matter for trial court discretion, reviewable only for abuse. See also *Lolie v. Ohio Brass Co.*, 502 F.2d 741 (7th Cir., 1974).

The Fourth Circuit failed to give proper deference to the latitude of the trial court discretion in this case, especially since here the independent evidence of liability was strong, and as has been pointed out, no argument was made or suggested that the issuance of the later warning was itself proof of the inadequacy of the 1974 warning.

II. THE FOURTH CIRCUIT HAS ERRONEOUSLY DECIDED OTHER IMPORTANT QUESTIONS OF FEDERAL LAW RELATING TO RULE 407, WHICH SHOULD BE SETTLED BY THIS COURT, NAMELY (A) THE APPLICABILITY OF RULE 407 TO THE ADMISSIBILITY OF EVIDENCE OF SUBSEQUENT REMEDIAL MEASURES TO PROVE BREACH OF EXPRESS WARRANTY AND (B) THE MEANING OF THE PROVISIONS OF RULE 407 THAT WHERE THE RULE APPLIES "EVIDENCE OF . . . SUBSEQUENT MEASURES IS NOT ADMISSIBLE TO PROVE NEGLIGENCE OR CULPABLE CONDUCT IN CONNECTION WITH THE EVENT."

A. *The Fourth Circuit erroneously held that Rule 407 precluded evidence of subsequent remedial measures to prove breach of express warranty.*

Again, though the opinion below concedes that Rule 407 "merely enacts the common law rule," the Fourth Circuit failed to give effect to the common law rule that evidence of subsequent remedial measures is admissible to prove breach of express warranty. See e.g., Chief Judge Thomsen's decision in *Becker Pretzel Bakeries, Inc. v. Universal Oven Co.*, 279 F. Supp. 893 (D.Md., 1968) (while "evidence of subsequent repairs may not be received as an admission of liability or as evidence of negligent construction," evidence that defendant ultimately cured condition complained of by correcting excessive slippage in meshes of oven held admissible to show that express warranty against defects in oven had been breached).

In the case at bar, Uphohn's package inserts and advertisements through 1974 described Cleocin as "indicated" in soft tissue infections, and set forth a recommended dosage for "mild" infections. These publications constituted an express warranty under the law of Maryland, where the sale took place, because they are "an affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain." Maryland Code, Commercial Law Article (Md. Unif. Comm. Code) § 2-313 (1). This affirmation or promise was false. Cleocin was *contra*indicated for plaintiff's condition, which involved a mild soft-tissue infection, and indeed contraindicated for any use by plaintiff under almost any circumstances, since plaintiff was not allergic to penicillin. The 1975 Cleocin instructional material says precisely this, and this in itself sufficiently establishes the breach of warranty. Liability for such a breach is not based on negligence or culpability, but upon whether the voluntarily undertaken affirmations or promises turn out in the event to be accurate.

Reversal of the Fourth Circuit on this point would finally dispose of all the respondents' grounds of appeal which have been passed on by the Fourth Circuit. The jury found for plaintiff on the warranty issue, and any claim of inconsistency between the jury's finding on the negligence and strict liability issues would be immaterial on the warranty issue. The dictum of the court below that "even were we to decide . . . [the warranty point] in plaintiff's favor a new trial would be required because the evidence was used to prove negligence" (Appendix A, p. 17a) is simply wrong because it overlooks the fact that the verdict is on separate issues. The finding on the warranty issue stands on its own and would support judgment for the plaintiff even if the finding on the negligence issue were overturned.

B. *The Fourth Circuit has misconstrued the provision of Rule 407 that where the rule applies "evidence of . . . subsequent measures is not admissible to prove negligence or culpable conduct in connection with the event" and has erroneously held that where expert witnesses have testified fully as to the impropriety of a 1974 warning and refer to a later warning only as an example of the kind of warning that would have satisfied their standards for a warning in 1974, the later warning was used "to prove negligence."*

In this case, the evidence of the subsequent instructions was not claimed to be an admission of negligence nor was the issuance of the later warning claimed as a basis for an inference that the earlier warning was negligent. The proof of negligence here consisted of expert testimony to the effect that given the knowledge of Upjohn in 1974, the 1974 warnings were inadequate because they did not contain information as to the possibility of fatal side effects, and they encouraged the use of Cleocin where, as in this case, that use was contraindicated and should have been warned against. The 1975 warning was pointed to as an example of the wording that the experts felt would have been suitable, and feasible, and on other issues in the case. Rule 407 prohibits only the admissibility of subsequent measures offered as proof of negligence and should not apply where the proof of negligence comes from explicit expert testimony and no argument is made or inference suggested that the giving of the subsequent warning is itself evidence of the fact that the earlier warning was negligent.

It is submitted that the use made of the evidence of the 1975 warning is not proscribed by the rule's provision against use of subsequent remedial measures "to prove negligence" especially in light of the limiting instruction given by the trial court, which admonished the jury that

the 1975 warning was "not to be considered as evidence of any negligence by Upjohn."[10]

III. THE QUESTIONS DISCUSSED IN POINTS I AND II ABOVE ARE SIGNIFICANT, RECURRING AND DESERVING OF THE ATTENTION OF THIS COURT BOTH BECAUSE OF THE INTER-CIRCUIT CONFLICTS THEY REFLECT AND THEIR OWN INTRINSIC IMPORTANCE FOR THE ADMINISTRATION OF CIVIL JUSTICE IN THE FEDERAL COURTS.

The Fourth Circuit's rejection of previous federal appellate authority as to the applicability, meaning and administration of Rule 407 makes action by this Court now necessary to achieve the uniformity of rules of evidence in the Federal Courts which has from the beginning been a primary purpose of the Federal Rules of Evidence. The stated object of the Rules was "to provide a uniform code of evidence in the Federal courts" [see H. Rep. No. 93-650, 28 USCA Federal Rules of Evidence p. 823]. The goal of uniformity was the inspiration for the rules starting from 1961, when the Judicial Conference of the United States first authorized the Chief Justice to appoint an Advisory Committee to study the advisability and feasibility of uniform rules of evidence for the Federal Courts. Senate Report No. 93-1277, 28 USCA Federal Rules of Evidence at p. 799; House Rep. No. 93-650, 28 USCA, Federal Rules of Evidence at 824-5. The fundamental purpose of the Rules can be achieved only if this

[10] The full instruction, which added that the evidence could be used "simply to indicate the feasibility of any precautionary measures that plaintiff suggests should have been taken" is (for reasons heretofore argued) more restrictive than it should have been. Far from being reversible error on Upjohn's appeal, it gave Upjohn more than Upjohn was entitled to.

Court settles intercircuit conflicts as to how the rules are to be interpreted and applied.

The questions raised in this case relate to a particularly controversial rule of evidence involving sensitive questions of policy with substantial practical consequences in significant classes of cases — Weinstein's Evidence (1977) pp. 407-6 to 407-12.[11] It is important that the substantive rights of the parties in products liability and other cases

[11] Petitioner has also raised one point relating to alleged inconsistency of verdict, for which the foregoing arguments for review by this Court cannot be made. The only basis on which counsel can conscientiously seek review on that issue is that if, as it is hoped, this Court grants certiorari, review of this issue as well should require only minimal effort and would enable this Court to do full justice. The issue is simple and the error below abundantly clear.

The opinion below argues that the jury's finding against Upjohn on negligence is necessarily inconsistent with the verdict in favor of Upjohn on strict liability. It has already been pointed out that strict liability can exist only if Cleocin was defective when it left Upjohn's hands, whereas Upjohn could be negligent for subsequent failure to use other means than the package insert to warn physicians and the public of possibly fatal side effects. There is also another reason why the verdicts are not inconsistent. The "strict liability" issue was submitted to the jury in a form which made it in effect something other than a strict liability issue, but which prejudiced only the plaintiff. Issue No. 5 asked, "Did the defendant Upjohn market or sell Cleocin in a defective condition unreasonably dangerous to those *more likely* to use it, which proximately caused or contributed to the injury of the plaintiff?" (Emphasis supplied) The comparative "more likely" required the jury to divide consumers into two groups based upon likelihood of use, and to find for plaintiff only if plaintiff was one of the group "more likely" to use Cleocin. This is not the same test as true strict liability, under which a defendant is liable where the product is in a defective condition "unreasonably dangerous to the user or consumer," Restatement of Torts 2d, 402A.

The persons "more likely" to use Cleocin are the persons for whom it is the drug of last resort — persons with certain serious and often life-threatening infections who cannot take penicillin and for whom less toxic drugs will not be effective. These patients were "more likely" to use Cleocin because the choice

involving substantial interests not be distorted by the kind of expansion of Rule 407 represented by the decision below. That decision creates new and unwarranted restrictions on the admissibility of evidence and subverts the general thrust of the rules, expressly declared in Rule 402, in favor of admissibiilty of all relevant evidence except as otherwise provided by some overriding provision of the Constitution, laws or applicable rules.

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would have been intelligent and almost inevitable, in spite of the risks. The jury could have found the warning not inadequate as to those patients because Cleocin was the drug to be used in any event and would have to be prescribed even in the face of adequate warning. Cleocin was unreasonably dangerous to those *least* likely to use it in the face of the 1974 warnings as actually given — those such as plaintiff, whose physician's negligence operated concurrently with the defective warning to produce injury and who were therefore less likely to use the drug than patients who really needed it.

The jury gave close attention to the way the issues were formulated. They asked for clarification of this issue quite possibly because they thought it was peculiar to have to answer it "No" in the light of their clear conclusion that the warning was not adequate, and that the inadequacy was a proximate cause of plaintiff's injury. Unfortunately, neither the court nor counsel perceived the legitimate ground of the jury's concern, and the judge merely reread his instructions on "strict liability." The jury, performing its duty to follow what the court in fact said, fairly answered the precise question addressed to them.

The verdict shows intelligence and perceptiveness, not confusion.

In any event, if the 1975 instructions are admissible to prove breach of express warranty, the issue of consistency of the verdict on negligence with that of strict liability would not have to be reached.

CONCLUSION

For the foregoing reasons, the writ of certiorari should be granted and the judgment of the Court of Appeals for the Fourth Circuit should be reversed.

Respectfully submitted,

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APPENDIX

Appeal from the United States District Court for the District of Maryland, at Baltimore. Joseph H. Young, District Judge.

Argued: March 8, 1979 *Decided: August 4, 1980*

Before RUSSELL and WIDENER, Circuit Judges, and MERHIGE, District Judge.*

WIDENER, Circuit Judge:

* Honorable Robert R. Merhige, United States District Judge for the Eastern District of Virginia, sitting by designation.

The plaintiff, Jack Werner, brought this action against the Upjohn Co. and Dr. Ralph J. Carbo, an opthamologist, to recover damages for injuries Werner received as result of his taking the prescription drug Cleocin which was manufactured by Upjohn and prescribed by Dr. Carbo. Jurisdiction is based on diversity of citizenship and the requisite amount in controversy.

The case was tried to a jury which found that Carbo was negligent in prescribing the drug and that his negligence proximately caused or contributed to plaintiff's injury; that Upjohn was negligent in either marketing or selling Cleocin and such negligence proximately caused or contributed to plaintiff's injury; that Upjohn was negligent in failing to warn properly of the dangerous side effects of Cleocin; that Upjohn breached either an express or implied warranty in its sale of Cleocin to Carbo; and that Upjohn

* Honorable Robert R. Merhige, United States District Judge for the Eastern District of Virginia, sitting by designation.

was not liable in strict liability for marketing an unreasonably dangerous drug. Based on these findings the jury awarded damages of $400,000. The defendants appeal.

Upjohn argues that there is insufficient evidence on which the jury could find that Upjohn was negligent; that the jury verdicts are inconsistent; that a subsequently revised warning was improperly admitted into evidence; that several of the jury instructions were improper; and that it could not be found liable even if the warning was inadequate because Dr. Carbo admitted that he did not read the warning which was given. Dr. Carbo argues that the plaintiff failed to establish the basic elements of a malpractice case; that the jury instructions were improper; and that, since the jury found Upjohn's warning inadequate and no other evidence of malpractice was present, the jury verdict against him cannot stand. Both defendants argue that it was error to refuse a jury instruction on contributory negligence and to fail to reduce the damage award to present value. The plaintiff filed a cross-appeal arguing that the trial court erred in refusing to allow the plaintiff to present evidence on punitive damages.

We hold that the district court erred in admitting the subsequent warning into evidence. We therefore reverse and remand for a new trial.

The prescription drug at the base of this action is Cleocin (generic name Clindamycin HC1) a broad-spectrum antibiotic. The Food and Drug Administration (FDA) first approved Cleocin for general use in 1970, and it soon became a popular alternative antibiotic for those persons who were allergic to penicillin. As the use of Cleocin increased Upjohn began to receive reports of side effects from Cleocin use, such as diahrrea and colitis. The appearance of these side effects was reported to the FDA and several medical studies were done both independently and by Upjohn which sought to clarify the incidence and extent of these side effects. The plaintiff argued that Upjohn knew of serious side effects in 1974 and failed to

act on this information until March 1975. Upjohn argued that its 1974 warning contained all the relevant information available at that time. In any event, as a result of the reported side effects and subsequent studies, the warning information accompanying Cleocin went through several revisions.[1] Throughout this period the central concern over Cleocin was its capacity to cause pseudomembranous colitis (PMC) in some patients. Prior to 1974 the incidence of PMC in Cleocin users was thought to be quite low, but in late 1973 a Dr. Tedesco published a study which found signs of PMC in 10 per cent of a test group who took the drug. However, it was not clear that the PMC found in Tedesco's patients was the same as the more commonly known and admittedly extremely serious PMC since Dr. Tedesco's patients recovered without any permanent problems. As a result of Tedesco's study and information provided by Upjohn and others a new warning was issued in the summer of 1974. This new warning was included in the package insert accompanying Cleocin and was the subject of what is called a "Dear Doctor" letter which was mailed to every physician in the United States. The adequacy of this warning at the time it was released is one of the central issues in this case. The 1974 warning stated:

WARNING

> Severe and persistent diarrhea, which may be accompanied by blood and mucus, and which may be associated with changes in large bowel mucosa diagnosed as "pseudomembranous colitis," has been reported in association with the administration of Cleocin HC1 (clindamycin HC1 hydrate).
>
> When significant diarrhea occurs (usually more than 5 bowel movements daily), the drug should be discontinued or, if necessary, continued only with close observation of the patient (large bowel endoscopy has been recommended). Mild cases of colitis may respond to drug discontinuance alone. Moderate

[1] The adequacy of the warnings issued prior to 1974 was not in issue in this case.

to severe cases should be managed promptly with fluid, electrolyte and protein supplementation as indicated. Antiperistaltic agents — opiates, meperidine, and diphenoxylate with atrophine may prolong and/or worsen the condition. Systemic corticoid and corticoid retention enemas may help relieve the colitis. Other causes of colitis should also be considered.

Note: Diarrhea has been observed to begin up to several weeks following cessation of therapy with Cleocin HC1. The physician must be alert to this possibility.

The plaintiff first visited Dr. Carbo in Maryland on December 10, 1974 for treatment of a chalazion on his eyelid. Dr. Carbo prescribed Cleocin for the plaintiff's condition and stated that he advised plaintiff that he might experience some nausea, vomiting or diarrhea, and told him that if he experienced these side effects he should stop using the drug and report to him. The plaintiff testified that Carbo gave him no such warning. Carbo's warning was based on the 1973 package insert. He admitted that he did not read the 1974 Dear Doctor letter before prescribing Cleocin to the plaintiff even though it was available in his office.

The plaintiff began to feel nauseous approximately five days after he started taking the drug and stopped using it. About a week later he reported this fact to Carbo who testified that he advised the plaintiff to discontinue the drug and call him if any further problems developed. Once again, plaintiff denied receiving this warning from Carbo. Several days later while in New York City the plaintiff developed severe diarrhea and dehydration. During this time he was taking Lomotil, an antiperistaltic agent, for the diarrhea which according to the 1974 warning (but not the 1973 warning) was contraindicated for PMC. On January 11, 1975, a Dr. Axelrod sigmoidiscoped the plaintiff and discovered the presence of PMC. He then questioned the plaintiff and determined for the first time that he had taken Cleocin. The Lomotil was discontinued

but the plaintiff's condition worsened. A large portion of his colon had to be removed and he underwent other operations to restore his excretory functions. The plaintiff presently is under dietary restrictions, has diarrhea, cannot engage in strenuous athletic activity, and tires easily.

As mentioned a central issue in the case against Upjohn and an important collateral issue in the case against Dr. Carbo was the adequacy of the 1974 warning, and both the plaintiff and Upjohn presented a great deal of evidence on the true dangers and incidence of side effects of Cleocin and whether the warning adequately conveyed the facts. Upjohn argued that the incidence of side effects was quite low and that if properly and timely treated the plaintiff would not have suffered permanent injury. Upjohn also relied heavily on the argument that everything which happened to the plaintiff was warned of in the 1974 warning. The plaintiff argued that, based on Upjohn's knowledge at the time the 1974 warning was released, the warning was inadequate and made Cleocin unreasonably dangerous and Upjohn negligent. Plaintiff also argued that even if the warning were adequate it was negated by Upjohn's advertising and the activities of Upjohn's detail men.

No evidence introduced by the plaintiff was more important on the adequacy of the 1974 warning, than the evidence he introduced, over objection, of a warning published in March 1975 which expanded on the 1974 warning. The 1975 warning stated:

> Clindamycin can cause severe colitis which may end fatally. Therefore, it should be reserved for serious infections where less toxic antimicrobial agents are inappropriate, as described in the INDICATIONS section. It should not be used in patients with nonbacterial infections, such as most upper respiratory tract infections. The colitis is usually characterized by severe, persistent diarrhea and severe abdominal cramps and may be associated with the passage

of blood and mucus. Endoscopic examination may reveal pseudomembranous colitis.

When significant diarrhea occurs, the drug should be discontinued or, if necessary, continued only with close observation of the patient. Large bowel endoscopy has been recommended.

Antiperistaltic agents such as opiates and diphenoxylate with atropine (Lomotil) may prolong and/or worsen the condition.

Diarrhea, colitis, and pseudomembranous colitis have been observed to begin up to several weeks following cessation of therapy with clindamycin.

Upjohn moved to exclude all reference to the 1975 warning. The court denied this motion and allowed the plaintiff to introduce the warning into evidence. When the warning was offered into evidence, over objection, the district judge instructed the jury that the warning was not to be used as evidence of negligence or culpable conduct. However, the court did not inform the jury at that time for what purpose it was to be considered. Later, after all evidence was in, the judge instructed the jury that they should only consider the 1975 warning on the issue of feasibility, obviously referring to Federal Rule of Evidence 407.

Federal Rule of Evidence 407, which enacts the common law rule excluding subsequent remedial measures to prove negligence, does, however, permit evidence of subsequent remedial measures to be used to prove the feasibility of such measures, but only if feasibility is controverted by the defendant. But, despite the judge's limiting instruction on this point it is clear that the 1975 warning was used by the plaintiff to prove negligence. The warning was mentioned several times during the course of the trial when expert witnesses were asked whether the information in the 1975 warning should have been included in the 1974 warning if that information had been available to Upjohn at the time the 1974 warning was given. This use of the warning has no conceivable connection to feasibility. The

plaintiff's expert witnesses were asked time after time whether Upjohn "should have" included the information in the 1975 warning in the 1974 warning. The obvious inference is that if Upjohn should have used the subsequent warning earlier, then it was negligent for failing to do what it "should have" done. This use of the 1975 warning clearly was impermissible and constitutes reversible error. *Columbia & Puget Sound R. Co. v. Hawthorne,* 144 U.S. 202 (1892).

Plaintiff argues that the defendant waived any objection along this line because it failed in its objection to state specifically the grounds for objection as required by Federal Rule of Evidence 103(a) (1). Rule 103(a) (1), however, requires specific objection only where the specific ground would not be clear from the context. In the case at bar, Upjohn, for example, had already filed a pre-trial motion with supporting memoranda asking that all references to the 1975 warning be suppressed. From our examination of the record, we have no doubt that the ground for objection was clear to everyone.

Plaintiff also made improper use of the 1975 warning in closing argument to the jury. Plaintiff's counsel stated:

> If we were to boil this down to the least common denominator, if you were to be asked tomorrow, after, hopefully, the case is decided and done with, what was the biggest single thing that Upjohn did wrong that impells [sic] you to bring in a verdict for the plaintiff against Upjohn, would you not have to say Upjohn knew of the fatalities and didn't tell the doctors until much later, after this whole episode was over and done? That they knew it should not be used for other than serious, life-threatening infections? That they knew there were other less toxic antibiotics which were appropriate, and they told people that later? That they knew that they had, according to their people, cut off promotion of the drug in the middle of '74, but didn't tell the doctors that? Don't you think, honestly, and you have to answer this to yourselves, don't you think any one of those four

> things was a violation of a duty which any ethical drug manufacturer owes the public, to keep the public informed, or keep the doctors informed so the public can be informed?
>
> Instead of that, they held it under their belt; they continued the advertising for at least four more months, in many instances. They held off the change until March of '75; [the date the 1975 warning was released] nine months after they knew this, and they cashed in as much as they could.
>
> * * * * * *
>
> But, in this delay, from July 1 to March of '75, before they really cut and told the doctors what they should have told them long ago, in that nine month period, . . .

The clear import of this argument is that Upjohn breached its duty of due care by failing to adopt the 1975 warning in 1974. Thus, plaintiff used the substance of the subsequent warning to prove antecedent negligence and thereby violated Rule 407. The defendant failed to object to the closing argument quoted above, but such an objection is not required in this circuit. *Leathers v. General Motors Corp.*, 546 F.2d 1083 (4th Cir. 1976). In *Leathers* during closing argument plaintiff's counsel had invoked the "Golden Rule" argument which in essence, asked the jury to decide the case as they would want it decided if they were the plaintiff. Despite lack of objection to the argument we reversed and remanded for a new trial stating that the defendant was not required to make a contemporaneous objection because to do so might only have emphasized the impermissible point and have antagonized the jury. The error in closing argument in the case at bar was at least as damaging as the argument in *Leathers*. Here, plaintiff was permitted to use evidence of subsequent remedial measures to argue negligence by Upjohn. Such argument is strictly forbidden by the policy-based Rule 407. If the Golden Rule argument is sufficiently out of bounds to excuse the contemporaneous objection re-

quirement then this clear violation of Rule 407 is no less so.

Plaintiff also argues that since an instruction was given limiting the use of the 1975 warning to the issue of feasibility that any error caused by plaintiff's departure from this rule is harmless because it was cured by the limiting instruction. This argument is without merit. In the abstract, of course, evidence may be admissible for one purpose and inadmissible for another. The usual solution for this problem is to admit the evidence to provide the permissible inference, but limit its use by jury instructions. This does not mean, however, that the party offering evidence for a limited purpose is free to use it for a forbidden purpose, over objection, during the course of the trial and insulate reversal by pointing to a limiting instruction given at the close of the case.

Plaintiff's position is further weakened by the fact that the feasibility of giving the 1975 warning in 1974 simply was not in issue in the case. As stated above, Rule 407 does allow evidence of subsequent remedial measures to be used to prove the feasibility of such measures, but only if feasibility is controverted by the defendant. The Advisory Committee Notes to Rule 407 state in terms that "unless a genuine issue" of feasibility is present the exception should not apply. The plaintiff contends that the issue of feasibility was controverted sufficiently to invoke the exception. His first argument is that no concession was made by defendant on this issue. However, it is clear from the face of the rule that an affirmative concession is not required. Rather, feasibility is not in issue unless controverted by the defendant.

In an effort to show a controverted issue of feasibility the plaintiff points to two statements Upjohn made to the FDA during negotiations on what was to be the exact content of the 1974 warning in which Upjohn purportedly argued that a stronger warning would be "misleading" or would have a "potential for much harm." When these

statements are examined in context it is apparent that plaintiff's argument is without merit. The first statement was made in reply to the FDA's suggestion that the phrase "and more rarely in PMC" be added to the 1974 warning. Upjohn's reply suggested a warning which stated: "Antibiotic associated 'PMC' can occur." In rejecting use of the word "rarely" Upjohn noted that Dr. Tedesco's study indicated that incidence was higher than "rarely" and that in general Upjohn preferred to avoid terms such as "rarely" or "infrequently", "since there is a distinct possibility of misleading." Thus, it appears that Upjohn's proposed exclusion of the word "rarely" strengthened, rather than weakened, the FDA's proposed warning, and certainly had nothing to do with controverting the feasibility of a stronger warning.

The second example cited by plaintiff arose out of an FDA request that the 1974 package insert include a warning that Cleocin not be used for minor infections. Such a warning ultimately was adopted in substance in the 1975 warning. In objecting to the FDA's proposal Upjohn stated that "there is no precise definition of minor or trivial infections and the physician is adequately guided by the limitation of the approved INDICATIONS. Such a statement has a potential for much harm and little or no benefit." The above quoted statement does not controvert the feasibility of writing a warning that Cleocin not be used for minor infections. It merely questions the necessity of such a warning. This distinction points up the basic position of Upjohn in this case that the 1974 warning was adequate. Upjohn does not argue that it could not have written a stronger warning, it argues that the 1974 warning was adequate given the knowledge it had at that time. This defense simply does not raise an issue of feasibility.

Thus, plaintiff's efforts to expand the feasibility exception must fail. Since feasibility was not in issue in the case the evidence should have been excluded. See Advisory Committee Notes to Rule 407. Rule 407 is designed to

protect the important policy of encouraging defendants to repair and improve their products and premises without the fear that such actions will be used later against them in a lawsuit. Several exceptions to the rule have developed, but it is clear that they must be narrowly construed if the central policy behind the rule is to be effectuated. If feasibility were to be found at issue in the case at bar, it is difficult to imagine a situation where it would not at least arguably be in issue. As Professor McCormick has said:

> [T]he extrinsic policy of encouraging remedial safety measures is the predominat reason for holding evidence of these measures to be privileged. It is apparent that the free admission of such evidence for purposes other than as admissions of negligence is likely to defeat this paramount policy. It is submitted that before admitting the evidence for any of these other purposes, the court should be satisfied that the issue on which it is offered is of substantial importance and is actually, and not merely formally in dispute, that the plaintiff cannot establish the fact to be inferred conveniently by other proof, and consequently that the need for the evidence outweighs the danger of its misuse.

McCormick on Evidence, § 275, at 668-69 (2d ed. 1972). In sum, feasibility is not in issue in this case, and even it if were, it is clear that the use made by the plaintiff of the 1975 warning was not so limited.

Alternately, plaintiff argues that even if the 1975 warning was not admissibile to show feasibility it was admissible on other grounds. It is arguable that this question is not directly before us on appeal because the 1975 warning was in fact used to prove negligence, and thus the fact that the evidence might have been admissible on some other ground not raised at trial should not prevent reversal and a new trial. Especially because this case must be tried again, and we do not believe that the 1975 warning was admissible, we examine plaintiff's other arguments for admitting the evidence.

Plaintiff argues, and we agree, that the exceptions listed in Rule 407 — ownership, control or feasibility of precautionary measures (if controverted), and impeachment, are illustrative and not exhaustive. See Advisory Committee Notes to Rule 407. However, we note once again that Rule 407 promotes an important policy of encouraging subsequent remedial measures. If this policy is to be effectuated we should not be too quick to read new exceptions into the rule because by so doing there is a danger of subverting the policy underlying the rule.

Plaintiff's principal argument along this line is that the 1975 warning is admissible because the suit includes a strict liability claim. The courts have split on this proposition. We suppose, without making a numerical comparison, that the majority of courts would admit the evidence for one reason or another. Compare e.g., *Smith v. E. R. Squibb & Sons, Inc.*, 273 N.W.2d 476 (Mich. 1979); *Price v. Buckingham Co.*, 110 N.J. Super. 462, 266 A.2d 140 (1970); with *Robbins v. Farmers Union Grain Terminal Ass'n.*, 552 F.2d 788 (8th Cir. 1977); *Ault v. Int'l Harvester*, 13 Cal. 3d 113, 117 Cal. Rptr. 812, 528 P.2d 1148 (1974).

In support of his argument to admit the evidence plaintiff first argues that Rule 407 in terms only bars the evidence to prove negligence or culpable conduct and that the rule therefore does not allow for exclusion on the strict liability issue. We disagree. The mere fact that Rule 407 by its terms only excludes evidence of subsequent precautionary measures to prove negligence or culpable conduct does not necessarily mean that the evidence should be admissible to prove strict liability.[2] It is clear that in enacting the Federal Rules of Evidence Congress did not intend to wipe out the years of common law development in the field of evidence, indeed the contrary is true. The new rules contain many gaps and omissions and in order to answer these unresolved questions courts

[2] We keep in mind Rule 402, that relevant evidence is generally admissible.

certainly should rely on common law precedent. See Redden & Saltzburg, *Federal Rules of Evidence Manual* 411-413 (1975). This is true with respect to Rule 407 which merely enacts the common law rule. Rule 407 bars evidence of subsequent precautionary measures to prove negligence or culpable conduct with exceptions for control, ownership or feasibility (if controverted) and impeachment. The rule simply does not speak in terms to the question of whether the evidence should come in to prove strict liability. To resolve this question we must examine the policy behind Rule 407 and the common law basis for the rule, and then determine if admitting the evidence as evidence of strict liability is more akin to the use of it to prove negligence, or if it is closer to one of the recognized exceptions to the rule. That is to say, would the policy behind the common law rule be served or subverted if evidence of subsequent precautionary measures be admitted to prove strict liability.

We first note that Rule 407 excludes evidence of subsequent precautionary measures to prove negligence or culpable conduct. Culpable conduct normally involves something more than simple negligence and implies conduct which is "blamable; censurable; involving the breach of a legal duty or the commission of a fault. . . . [I]t implies that the act or conduct spoken of is reprehensible or wrong, but not that it involves malice or a guilty purpose." *Black's Law Dictionary* (4th ed. 1968). Thus, Congress has determined that such evidence should be excluded not only in cases involving negligence but where the defendant is charged with culpable conduct. Strict liability on the other hand involves conduct which is technically less blameworthy than simple negligence, since the plaintiff need not prove a breach of duty by the defendant other than placing the product on the market. From a policy standpoint it follows that if the rule expressly excludes evidence of subsequent repairs to prove culpable conduct that the same should be true for strict liability. Stated another way, if the common law and Congress were willing to exclude the evidence on the issue

of culpable conduct, the result should be no different on policy grounds as long as strict liability is not distinguishable on some other ground.

Plaintiff argues that a fundamental distinction exists between negligence and strict liability since in a negligence action it is the reasonableness of the defendant's conduct which is in issue while in a strict liability case the issue is whether the product is unreasonably dangerous. Thus, the argument goes, in a negligence action the focus is on the defendant while in strict liability the focus is on the product. We concede the obvious distinction between negligence and strict liability, but we do not believe that this distinction should product a different result. The rationale behind Rule 407 is that people in general would be less likely to take subsequent remedial measures if their repairs or improvements would be used against them in a lawsuit arising out of a prior accident. By excluding this evidence defendants are encouraged to make such improvements. It is difficult to understand why this policy should apply any differently where the complaint is based on strict liability as well as negligence. From a defendant's point of view it is the fact that the evidence may be used against him which will inhibit subsequent repairs or improvement. It makes no difference to the defendant on what theory the evidence is admitted; his inclination to make subsequent improvements will be similarly repressed. The reasoning behind this asserted distinction we believe to be hypertechnical, for the suit is against the manufacturer, not against the product.

Of course, exceptions must arise where the defendant attempts to make offensive use of the exclusion of this evidence. Thus, if the defendant denies ownership or control, contends that no such repair or improvement was possible, or makes statements conflicting with the fact of repair, then the plaintiff should be allowed to make use of subsequent remedial measures. As previously noted, the list of exceptions in Rule 407 is illustrative, not exhaustive, but each of the listed exceptions deals with situations

where the defendant might gain a direct benefit over and above the fact of exclusion and it seems to us that new exceptions to the rule should follow this rationale if the policy behind the rule is to be protected.

The defendant argues that we should adopt the rule of some courts, that the rule against admitting evidence of subsequent remedial measures not apply in product liability cases. See *Ault v. Int'l Harvester,* 13 Cal. 3d 113, 117 Cal. Rptr. 812, 528 P.2d 1148 (1974). We are not persuaded. The court assumes that the product is defective, and thus overlooks the situation where the product is not defective but could be made better. The manufacturer who undertakes precautionary measures in this setting will face the risk of liability for an injury caused by the earlier nondefective version of the product based on evidence of his subsequent act which made the product safer but in no way supports an inference that the initial version of the product was defective. Furthermore, if the rationale of *Ault* were applied in federal courts it might effectively override Rule 407 since its reasoning that evidence of subsequent precautionary measures is admissible in product liability cases might apply with equal force to a negligence cause of action. However, Congress, in enacting Rule 407, has chosen to exclude such evidence as proof of negligence and the *Ault* court offers no basis for distinguishing between the two theories. *Smyth v. The Upjohn Company,* 529 F.2d 803 (2nd Cir. 1975) rejects the holding of *Ault* as do we.[3]

Our conclusion is supported by the close similarity between negligence and strict liability. The elements of both are the same with the exception that in negligence plaintiff must show a breach of a duty of due care by defendant while in strict liability plaintiff must show the product was unreasonably dangerous. The distinction between the two lessons considerably in failure to warn cases since it is clear that strict liability adds little in

[3] The Appellate Division in New York has not followed *Smyth,* however. *Barry v. Mangloss,* 55 A.D.2d 1, 389 N.Y.S.2d 870 (1976).

warning cases. Under a negligence theory the issue is whether the defendant exercised due care in formulating and updating the warning, while under a strict liability theory the issue is whether the lack of a proper warning made the product unreasonably dangerous. Though phrased differently the issue under either theory is essentially the same: was the warning adequate? *Chambers v. G. G. Searle & Co.*, 441 F. Supp. 377, 381 (D. Md. 1975), aff'd 567 F.2d 269 (4th Cir. 1977); *Smith v. E. R. Squibb & Sons, Inc.*, 273 N.E.2d 476, 480 (Mich. 1979); Prosser, *Torts* § 99, esp. p. 659 n. 73 (4th ed. 1971).

Any remaining distinction in theories disappears when a failure to warn case involves an unavoidably dangerous drug which the product in this case admittedly was. The Restatement of Torts (2d) § 402A, comment k makes it clear that a drug manufacturer is not to be held strictly liable for injuries caused by an unavoidably dangerous new drug if the warning is adequate.[4] The standard for

[4] k. *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict

liability under strict liability and negligence is essentially the same. *Chambers, supra* at 381.

Since the issue under either theory is the same, a decision which admits evidence of subsequent remedial measures on a strict liability theory in a failure to warn case involving an unavoidably dangerous drug would promote substance over form and subvert the policy behind excluding evidence of subsequent remedial measures. We decline the invitation to follow the other courts which may have so held, and prefer the reasoning of *Chambers,* exactly to the point here, and *Smith,* very nearly so.

The plaintiff also argues that the 1975 warning is admissible to prove breach of an express warranty, to prove causation, or to show that plaintiff was entitled to punitive damages. Once again, even were we to decide any of these points in plaintiff's favor a new trial would be required because the evidence was used to prove negligence. In any event, we hold, for the same reasons stated in our refusal to allow the 1975 warning to come in to prove strict liability, that the policy behind Rule 407 does not allow for a new exception to prove causation, breach of express warranty or entitlement to punitive damages on the facts of this case.

Plaintiff's final argument on the admissibility of the 1975 warning is that it was required by the FDA, and that since defendant Upjohn had no choice in the matter, the policy behind Rule 407 would not be served by excluding the evidence. While this argument may have a surface plausibility, we do not believe the evidence should be admitted for this reason. First, when a third party has required the change the relevance of the evidence is one more step removed from the central issue in the case, the adequacy of the warning at the time the product was

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liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

marketed. When a third party makes a subsequent change the inference is removed not only in time but in who made the change. This is especially true in the case at bar since the FDA itself approved the 1974 warning at the time it was first used. Thus, it would appear that any separate relevance of the FDA's actions with regard to the 1975 warning is overridden by the fact that the FDA approved the 1974 warning as well.

Furthermore, plaintiff's argument overlooks the dual responsibility for preparing warnings for prescription drugs. The FDA can require that a warning be changed, but this does not tell the whole story. In addition to its broad regulatory sanctions it is clear that it also relies on voluntary compliance and compromise in determining the content of warnings and advertising for prescription drugs. See Dixon, *Drug Product Liability* § 5.05. This cooperative aspect of prescription drug regulation is apparent in the correspondence between Upjohn and FDA in the case at bar in arriving at warnings and their changes. Furthermore, FDA regulations allow drug companies to change the labels and warnings accompanying their products without prior FDA approval where new side effects are discovered by the company. 21 C. F. R. § 314.8(d)-(e). Subsection (d) states in pertinent part:

> (d) Changes of the following kinds proposed in supplemental new-drug applications should be placed into effect at the earliest possible time:
>
> > (1) The addition to package labeling, promotional labeling, and prescription drug advertising of additional warning, contraindication, side-effect, and pre-caution information.

Subsection (e) states:

> (e) It will be the policy of the Food and Drug Administration to take no action against a drug or applicant solely because changes of the kinds described in paragraph (d) of this section are placed in effect by the applicant prior to his receipt of a written notice of approval of the supplemental new-drug

application: *Provided,* That all the following conditions are met:

> (1) The supplemental new-drug application providing a full explanation of the basis for the changes has been submitted, plainly marked on the mailing cover and on the supplement "Special new-drug application supplement — Changes being effected."
>
> (2) The applicant specifically informs the Food and Drug Administration of the date on which such changes are being effected, and submits to the Administration 12 printed copies of any revised labeling to be placed in use, identified with the new-drug application number.
>
> (3) All promotional labeling and all drug advertising are promptly revised consistent with the changes made in the labeling on or within the drug package.

The quoted regulations demonstrate that plaintiff's argument is without merit. If subsequent warnings are admitted to prove antecedent negligence simply because FDA required or might have required the change, then drug companies may be discouraged from taking early action on their own and from participating fully in voluntary complaince procedures. Thus, we think that the FDA's regulatory power should not be read as in conflict with the protective policy of Rule 407. The FDA's regulations and policies encourage early unilateral action by the drug companies to improve their warnings, and Rule 407 promotes the same goal. We therefore hold that FDA regulations in the area of drug labeling do not require a new exception to Rule 407. Indeed, to find such an exception would subvert the policy goals of both Rule 407 and FDA Regulations 314.8(d)-(e).

One further point deserves specific mention for it serves as an alternate ground for a new trial for Upjohn. It is claimed that the verdict for Upjohn on the issue of strict liability is inconsistent with the verdict against Upjohn on

the issue of negligence. We agree. The effect of the jury verdict on negligence was to find that Upjohn failed to use due care to give an adequate warning of the propensities of the drug marketed, and, in the same breath, the verdict on strict liability found that the drug marketed with such an inadequate warning was not unreasonably dangerous. The verdicts in the context of this failure to warn case involving prescription drugs are obviously inconsistent and cannot stand. The same may be said of the verdict against Upjohn so far as it may be upon an implied warranty, for the only evidence that the drug was not reasonably fit concerned the warning.

There are other claims of error, many of which concern the sufficiency of evidence, including a cross appeal claiming error in refusing to submit the question of punitive damages to the jury. We express no opinion on any of these, since the case must be tried again and the questions now before us may not come up in a new trial or be presented in a different form upon somewhat different facts. We are not obligated in each case to pass upon claims concerning sufficiency of evidence, *Stonehocker v. General Motors,* 507 F.2d 151 (4th Cir. 1978), and we think this is a case in which we should not do so.

We also vacate the judgment against Dr. Carbo and remand for a new trial. It is true that most of our discussion has concerned the adequacy of the warning given by Upjohn, but much, or even most, of the trial was devoted to that subject. There is no doubt the whole trial centered about that question. Dr. Carbo's duty to his patient was so bound up in the warnings given by Upjohn, that we do not believe a judgment against him should be allowed to stand when the record contains error going to the most fundamental question in the case: the adequacy of the warning. The probability of prejudice is too great. Under 28 U.S.C. § 2106, we think the judgment against Dr. Carbo must also be vacated and remanded for a new

trial. *United States v. Caudle, et al.*, ____ F.2d ____, Nos. 79-5013 and 5014 (4th Cir. October 5, 1979).

The judgment appealed from must be vacated and the case remanded for a new trial.

Vacated and Remanded.

JUDGMENT

United States Court of Appeals

for the Fourth Circuit

No. 78-1092

Jack Werner,

Appellant,

v.

Ralph J. Carbo, Jr., M.D. and Ralph J. Carbo, Jr., M.D., P.A., a body of corporate Maryland, and The Upjohn Company, Inc., a body corporate of the State of Delaware,

Appellees.

Appeal from the United States District Court for the District of Maryland.

This cause came on to be heard on the record from the United States District Court for the District of Maryland, and was argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the said District Court appealed from, in this cause, be, and the same is hereby, vacated. The case is remanded to the

United States District Court for the District of Maryland, at Baltimore, for a new trial consistent with the opinion of this Court filed herewith.

/s/ WILLIAM K. SLATE, II,
Clerk.

PROOF OF SERVICE

The undersigned counsel, a member of the Bar of this Court, hereby certifies pursuant to Rule 28 that he has served the foregoing Petition for Writ of Certiorari upon all parties required to be served, namely, The Upjohn Company, Inc., a body corporate of the State of Delaware, 301 Heneritta Street, Kalamazoo, Michigan, and Ralph J. Carbo, Jr., M.D., 50 West Edmonston Drive, Rockville, Maryland 20852, by depositing on October 24, 1980, three copies of the Petition in the United States Post Office branch located at Fayette and Calvert Streets, Baltimore, Maryland, with first-class postage prepaid addressed to the counsel of record for each of the parties in the Court of Appeals other than the petitioner. The said counsel of record upon each of whom service of three copies was so made are M. King Hill, Jr., Esquire, Smith, Somerville and Case, Sixth Floor, 100 Light Street, Baltimore, Maryland 21202, attorneys for The Upjohn Company, Inc.; and Roy L. Mason, Esquire, Suite 708 Unibank Building, 51 Monroe Street, Rockville, Maryland 20850, attorney for Ralph J. Carbo, Jr., M.D.

The caption of the opinion and judgment of the Fourth Circuit in the above case names as an additional party, Ralph J. Carbo, Jr., M.D., P.A., a body corporate of Maryland. The incorporated professional association was named in the original Complaint in the United States District Court for the District of Maryland, and judgment was entered against it in the District Court but no notice of appeal was filed on behalf of the corporation.

The professional corporation was thus not in fact a party in the Court of Appeals, and was not named as a party in the caption of the joint record extract or any brief in the Court of Appeals, or in the text of the opinion of the Court of Appeals. The Court of Appeals was therefore without jurisdiction to affect the judgment against the corporation.

In any event, the same office as was counsel of record for Dr. Carbo in the Court of Appeals was counsel of record for the professional corporation as well as Dr. Carbo in the District Court. Consequently, the requisite number of copies have been served on "each other party separately represented" (Rule 28.3), and all service required by the rule has been made.

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Supreme Court, U.S.
FILED
NOV 26 1980
MICHAEL RODAK, JR., CLERK

No. 80-680

In the
Supreme Court of the United States
October Term, 1980

JACK WERNER,
Petitioner

v.

THE UPJOHN COMPANY, INC., and
RALPH J. CARBO, JR., M.D.,
Respondents.

BRIEF IN RESPONSE TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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November 26, 1980

THE CASILLAS PRESS, INC.–1717 K Street, N. W.–Washington, D. C.–223-1220

In the

Supreme Court of the United States

October Term, 1980

No. 80-680

JACK WERNER,

Petitioner

v.

THE UPJOHN COMPANY, INC., and
RALPH J. CARBO, JR., M.D.,

Respondents.

BRIEF IN RESPONSE TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

STATEMENT OF FACTS

The respondent, Ralph J. Carbo, Jr., M.D., hereby adopts and incorporates, for the limited and exclusive purpose of his Response to Petition for Certiorari, the Statement of Facts made by the co-respondent, The Upjohn Company, Inc., in its Response to the Petition for Certiorari filed herein.

ARGUMENT

The respondent, Ralph J. Carbo, Jr., M.D., hereby adopts and incorporates the argument made by the co-respondent, The Upjohn Company, Inc., in its Response to the Petition for Certiorari filed herein.

CONCLUSION

For the reasons set forth by respondent The Upjohn Company, Inc., which are adopted and incorporated herein, respondent Carbo urges that the Writ of Certiorari be issued so that the judgment and opinion of the Court of Appeals for the Fourth Circuit may be reviewed and affirmed.

Respectfully submitted,

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80-680

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IN THE

Supreme Court of the United States

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RESPONDENTS' BRIEF

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QUESTIONS PRESENTED

1. Did the Fourth Circuit correctly hold that the trial court committed reversible error in permitting the plaintiffs to use evidence of a warning issued subsequent to the date of ingestion of defendant's drug by plaintiff for the sole purpose of proving culpable conduct on the part of defendant, after the evidence of the subsequent warning had been offered and admitted solely for the purpose of proving the feasibility of giving the subsequent warning at an earlier date?

2. Did the Fourth Circuit correctly hold that evidence of a subsequent warning after the date of ingestion of defendant's drug by plaintiff was not admissible to show the feasibility of giving the subsequent warning at an earlier date when the feasibility of giving a different warning prior to the date of ingestion of the drug was not controverted by the defendant?

3. Did the Fourth Circuit correctly hold that in a drug liability case, where the product is an unavoidably unsafe product and where the sole issue on the liability of the defendant drug company is the adequacy of the accompanying warning in the package insert, all issues of liability of the defendant involve proof of culpable conduct under the applicable Maryland law, thus precluding admission into evidence of a subsequent warning when the evidence is offered and used by counsel to prove culpable conduct on the part of the defendant?

4. Did the Fourth Circuit correctly hold that in a drug liability case, where the sole issue was the adequacy of the defendant's warning, an answer by the jury on issues that the defendant was guilty of negligence because of the inadequacy of the warning was totally inconsistent with the answer of the jury on strict liability that the warning was not inadequate so as to create totally inconsistent answers to the issues, thus requiring a new trial?

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I. Because the basis of the Fourth Circuit's reversal was a holding that the trial court erred in permitting the plaintiff to use the evidence of the subsequent warning for the sole purpose of proving culpable conduct on the part of the defendant, contrary to the provisions of Rule 407 of the Federal Rules of Evidence, with an alternative holding that the jury's verdicts as to negligence and strict liability were inconsistent, and because the Fourth Circuit's view on the inadmissibility of the subsequent warning on other issues was mere dicta offered solely for guidance upon retrial in the interests of time and judicial economy, there is no important issue of federal law which is ripe for review and settlement by this Court or which is in conflict with the decision of any other circuit. 10

II. The dicta of the Court of Appeals relating to the inadmissibility of the evidence of the subsequent warning, which was given for guidance to the District Court on retrial, is not in conflict with the decision of the Eighth Circuit in *Robbins*, since the two cases are clearly distinguishable and reconcilable both factually and legally. 18

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A. The Fourth Circuit correctly stated that in the context of this drug liability case, where the sole issue is the adequacy of the warning, evidence of a subsequent warning is inadmissible on the issues of strict liability and breach of warranty, and this statement is not in conflict with the Eighth Circuit's decision in *Robbins* 18

B. The Fourth Circuit correctly stated that the evidence of the subsequent warning did not become admissible under Rule 407 merely because the subsequent warning was required by the Food and Drug Administration. This statement is not in conflict with any decisions of other Circuit Courts of Appeals. 22

C. The Fourth Circuit correctly stated that evidence of a subsequent warning is not admissible as evidence of the feasibility of giving a warning different from that actually given, where such feasibility was not in fact controverted by Upjohn. This statement is not in conflict with the decision of the Court of Appeals of another circuit 27

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SUMMARY OF ARGUMENT

I. The Fourth Circuit decision is not in conflict with the decisions of other Federal Courts of Appeals on the applicability, scope, interpretation and administration of Rule 407 of the Federal Rules of Evidence.

A. The Fourth Circuit's reversal of the trial court was based on the improper use of the evidence of the subsequent warning to prove culpable conduct on the part of the defendant contrary to the express provisions of Rule 407 of the Federal Rules of Evidence. This holding is not in conflict with the decisions of other Federal Courts of Appeals.

B. The Fourth Circuit's alternative ground of reversal that the findings of the jury on the issues of negligence and breach of warranty were directly in conflict with the jury's finding on the issue of strict liability was entirely correct, and Petitioner concedes that this issue is not a proper one for review by way of writ of certiorari.

C. The Fourth Circuit's decision on the admissibility of evidence of the subsequent warning on the issues of strict liability, breach of warranty, causation, and feasibility was mere dicta for the guidance of the trial court upon retrial. Accordingly, the "decision" on these issues cannot be in conflict with the decision of the Eighth Circuit. Moreover, because of sharp differences between the facts, procedural issues and the applicability of state law in the decisions of the Fourth Circuit and the Eighth Circuit, there is no direct conflict between the two decisions which would be necessary, desirable or practical for this Court to resolve.

D. The statement of the Fourth Circuit in dicta that evidence of the subsequent warning did not become

admissible under Rule 407 because the warning was required by the Food and Drug Administration is clearly correct and is not in conflict with any decision of another Circuit Court of Appeals.

E. The Fourth Circuit decision that evidence of a subsequent warning is not admissible as evidence of feasibility when feasibility is not controverted involves a clear and settled application of Rule 407, and its determination that the issue of feasibility was not "controverted" was not in conflict with a decision of any other Court of Appeals. Accordingly, the issue is not a proper one for review by way of writ of certiorari.

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WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

RESPONDENTS' BRIEF

STATEMENT OF THE CASE

Because respondent believes that petitioner's statement of the facts of the case beginning at page 4 of petitioner's brief is a biased and inaccurate statement of the facts as set forth in the record extract in the Fourth Circuit and the facts as noted by the Fourth Circuit, respondent believes that it is necessary to restate the facts with appropriate citations to the record extract below. References to "App." refer to the Joint Appendix in the Court of Appeals. References to "T." refer to the transcript of the proceedings in the District Court. References to "P. App." refer to the Appendix in Petitioner's Writ of Certiorari.

A. *Background and Development of Cleocin.*

Before 1965, The Upjohn Company sold a broad-spectrum antibiotic known as Lincocin. Lincocin's primary side effects were intestinal upset, diarrhea, and various forms of colitis with varying degrees of severity (App. 597-98). These side effects had also been reported from the use of most other antibiotics, including penicillin and tetracycline (App. 212, 215, 223-24). Because Lincocin had a higher reported incidence of gastric side effects than some of the other antibiotics, Upjohn developed Cleocin,[1] a synthetic analog of Lincocin (App. 201), in approximately 1965.

After laboratory testing for efficacy, Cleocin was extensively tested in animals and humans before it was approved for marketing by the Food and Drug Administration (FDA) in 1970 (App. 383-84). This research indicated that Cleocin had a much lower incidence of diarrhea and gastric upset than Lincocin (Plaintiff's Ex. 12, App. 498). In clinical studies on 5500 patients, there was not one reported incident of colitis (App. 404-05).

Cleocin was approved by the FDA for marketing in 1970 with a "package insert" containing its indications for use and statements of adverse reactions (Plaintiff's Ex. 56A, App. 564). A package insert is the literature distributed with each package of a drug; it contains the recommended indications for use and

[1] Cleocin is the trade name for the generic Clindamycin.

warnings of known or possible side effects. This insert must be approved by the FDA and published with any announcement or advertisement for the drug, and it must accompany any literature concerning the drug distributed to physicians (App. 386-87). The package insert also appears verbatim in the *Physicians Desk Reference* (PDR), a yearly publication containing such inserts for all prescription drugs on the market.

Cleocin was found to be an important and extremely effective broad-spectrum antibiotic (App. 345). It was widely used as an alternative to penicillin for persons who were penicillin allergic and for patients who could not tolerate other antibiotics (App. 345). It was used throughout the country and extensively in the Maryland medical community (App. 353).

As the use of Cleocin became more widespread, Upjohn began to receive reports of diarrhea and colitis as adverse reactions (App. 387-88). Upjohn thoroughly investigated these reports and forwarded them to the FDA (App. 388). The reports resulted in a series of changes in the warnings accompanying Cleocin (App. 387). The series of changes up to 1973 generally stengthened the warnings and included additional indications of reported side effects (Plaintiff's Ex. 56A). All changes were approved by the FDA (App. 387).

In 1973, a number of articles appeared in medical journals noting clinical cases of colitis following ingestion of Cleocin (Plaintiff's Exs. 10, 58). Each article was reported to the FDA (App. 388-89). The true incidence of diarrhea, colitis and acute colitis was difficult to determine because the only basis for accumulating incidence data after these articles began to appear was the adverse reaction reports submitted by the medical community to Upjohn (see Upjohn Ex. 11, App. 604-05). Based on well accepted indices prepared by independent agencies, Upjohn estimated that, up to August 1974, 15.7 million persons had been treated with Cleocin, yet Upjohn had received only 209 reports of colitis (App. 401-02).

B. *Dr. Tedesco's Study*

Because of the reports of colitis in both the literature and the adverse reaction reports, Upjohn in 1973, initiated four studies of Cleocin patients (App. 389), one of which was a prospective study by Dr. Francis Joseph Tedesco at Barnes

Hospital in St. Louis (App. 180). The final results of Tedesco's study were sent to Upjohn in late April of 1974 (App. 185; Plaintiff's Ex. 31, App. 500), although interim reports had been sent in late 1973 (App. 499). Upjohn forwarded Tedesco's reports to the FDA at the various stages of completion (App. 416).

Dr. Tedesco, who testified as the plaintiff's expert, found diarrhea in 21 percent of the patients using Cleocin in Barnes Hospital and, on sigmoidoscopic examination, signs of pseudomembranous colitis (PMC) in 10 percent (App. 183, 500). PMC was generally known at the time to be an extremely serious disease with a mortality rate between 50 and 75 percent (App. 218). While Dr. Tedesco made these findings in a patient population of only 200, he was the first physician in making such a study to sigmoidoscope most of the Cleocin patients who developed diarrhea (T. 396). Most significantly, however, Tedesco's study revealed that Cleocin-induced PMC was not the kind of serious disease process that had previously been associated with PMC, but rather was one that was benign and self-limiting (App. 501). All of Tesesco's patients in the study recovered (App. 221), and Dr. Tedesco found that if PMC were diagnosed and treated promptly, no serious complications would be likely to develop (App. 222), with recovery expected in most instances in four to seven days (App. 501). Thus, Tedesco agreed that the incidence of "serious" colitis, in relation to his study, depended upon how one defined "serious" (App. 189), since there was no clearly understood definition of that term in the medical community (App. 226). Even Tedesco defined "serious colitis" as only those cases where that patients had been in the hospital for weeks suffering from severe medical complications (App. 226). Tedesco's 10 percent incidence finding was admittedly, therefore, not an indication that 10 percent of the population would contract "serious" colitis from the ingestion of Cleocin.

C. *The Kalamazoo Meeting*

In November 1974, following the publication of Dr. Tedesco's study (App. 441), Upjohn invited several professors of medicine to attend a meeting at Upjohn's offices in

Kalamazoo (App. 440). These persons were all chiefs of infectious disease divisions of their respective medical schools (App. 440). Dr. Frank Calia of the University of Maryland was one of these experts (App. 429, 440), and he subsequently testified on behalf of Upjohn.

The purpose of the meeting was twofold: to educate the experts as to the data sent to Upjohn concerning PMC and to obtain recommendations from these experts with respect to designing further incidence studies of Cleocin's side effects (App. 441). All adverse reaction reports, including all serious colitis and mortality cases, were made available to and were reviewed by the experts (App. 441). As related by Dr. Calia, Upjohn "took us into a room, laid [the data] on the table, . . . and the company officials left and left us alone" (App. 441). A number of recommendations for further study resulted from that meeting (App. 441). Dr. Calia subsequently testified that, in his opinion, the 1974 package insert was entirely adequate to inform a reasonably competent physician of the adverse reactions and side effects from the use of Cleocin (App. 435).

D. *The 1974 Package Insert and "Dear Doctor" Letter*

In the summer of 1974, following the receipt of Tedesco's study, Upjohn and the FDA corresponded and met frequently concerning possible revision of the Cleocin package insert (Upjohn's Exs. 8 - 14, App. 599-630). These contacts resulted in Upjohn changing the warnings for Cleocin, with the approval of the FDA, in August 1974 (Upjohn's Exs. 13 and 14, App. 622-23). The new package insert instituted a "black box" warning, which read as follows:

WARNING

Severe and persistent diarrhea, which may be accompanied by blood and mucus, and which may be associated with changes in large bowel mucosa diagnosed as "pesudomembranous colitis," has been reported in asoociation with the administration of Cleocin HC1 (clindamycin HC1 hydrate).

When significant diarrhea occurs (usually more than 5 bowel movements daily), the drug should be discontinued

or, if necessary, continued only with close observation of the patient (large bowel endoscopy has been recommended). Mild cases of colitis may respond to drug discontinuance alone. Moderate to severe cases should be managed promptly with fluid, electrolyte and protein supplementation as indicated. Antiperistaltic agents – opiates, meperidine, and diphenoxylate and atropine may prolong and/or worsen the condition. Systemic corticoids and corticoid retention enemas may help relieve the colitis. Other causes of colitis should also be considered.

Note: Diarrhea has been observed to begin up to several weeks following cessation of therapy with Cleocin HCl. The physician must be alert to this possibility.

Three additional changes had been suggested by some FDA personnel. First, some wanted a specific warning that deaths had resulted from PMC (T. 921; Plaintiff's Exhibit 37). Other persons at the FDA (T. 925; Plaintiff's Exhibit 38) and at Upjohn thought this totally unnecessary, since the disease process "pseudomembranous colitis" noted in the new warning was still generally known to be a serious complication and one that had a very high mortality rate, according to all of the medical experts who testified at trial (App. 217-18). Second, the FDA suggested language that Cleocin was known to cause colitis "and rarely pseudomembranous colitis." (App. 391-92; Upjohn Ex. 8, App. 599). Upjohn replied that it would not be accurate to add "and rarely pseudomembranous colitis" in view of the conflicting incidence figures dramatized by Dr. Tedesco's recent study (App. 393-94); Upjohn Ex. 10, App. 601). Finally, some FDA personnel suggested language recommending that Cleocin not be used for "minor" or "trivial" infections, an addition Upjohn opposed because such a statement was applicable to antibiotics generally (Plaintiff's Ex. 37, App. 504, 507). None of these changes were required by the FDA in 1974.

Coincident with the FDA approval of the 1974 black-box warning for Cleocin, Upjohn, with the approval of the FDA, prepared a "Dear Doctor" letter, which was mailed with the new package insert to every physician in the United States. It was stipulated that the "Dear Doctor" letter containing the new adverse reaction warnings and the new package inserts was

mailed to Dr. Carbo on August 17, 1974 (App. 136-37). Carbo could not say that he did not receive the material and could not deny that it was received (App. 301). In October 1974, the new warning was also published in Supplement B to the 1974 PDR. Supplement B was admittedly available in Dr. Carbo's office by December 1974 (App. 299-300), when he prescribed Cleocin for the plaintiff.

The August 1974 package insert and the "Dear Doctor" letter dated August 16, 1974 (Plaintiff's Ex. 38, App. 514), contained substantially all of the recommendations suggested by Dr. Tedesco in his report (App. 216-17, 240), except that Tedesco's specific incidence data were not published. Upjohn felt that Tedesco's findings could not be accepted, without further study, as indicating the true incidence of serious colitis. Tedesco's study had a tiny population (200 patients) as contrasted with the 15.7 million people that Upjohn knew had ingested Cleocin as of 1974, and from which Upjohn had received reports of only 209 cases of colitis (App. 402). Further, the antibiotic-induced PMC found by Tedesco could not be equated with "serious" colitis (App. 435) because most of Tedesco's patients were not seriously ill (App. 400), all recovered, and Tedesco himself described the disease as benign and self-limiting (App. 501). Accordingly, Upjohn was reluctant to generalize from Tedesco's limited data (App. 393; Upjohn Ex. 10, App. 601). Meanwhile, Upjohn continued existing studies (App. 389), continued to finance further Tedesco studies (App. 389), and initiated others (App. 389), all in an effort to verify the Tedesco findings. These later studies found much lower incidences of Cleocin-related diarrhea and PMC than Tedesco had found (T. 494-511, 515-18, 626-28, 801-03, 816-20, 856-57) and even today the true incidence of Cleocin-related PMC and serious colitis is hotly in dispute (App. 434-35).

In preparing its "Dear Doctor" letter in August of 1974, Upjohn treated every case of colitis reported to Upjohn as a case of "serious colitis" and, using these figures as the best available incidence data at that time, reported an incidence of one in 50,000 to one in 100,000 cases of serious colitis among persons taking the drug (App. 402-05). This incidence did not purport to be that for Cleocin-related PMC, but only for

"serious" colitis resulting from the drug. The "Dear Doctor" letter indicated that the incidence data was difficult to project at that time and discussed the factors that made obtaining a true incidence figure difficult (App. 515). Like the August 1974 package insert, the "Dear Doctor" letter was approved by the FDA before publication (App. 400).

After the revision of the package insert in August of 1974, Upjohn decided to discontinue promotion of the oral form of Cleocin (App. 407). This decision was based largely on the fact that Upjohn had been advised that there would be a meeting of the FDA Infectious Disease Advisory Committee sometime in the fall of 1974, where there would be a full discussion of Cleocin-induced colitis and PMC; that both the FDA and Upjohn would have the benefit of the expertise of the Advisory Committee after the meeting took place; and that the meeting would probably result in further revisions of the package insert and cautionary warnings (App. 407, 423). Upjohn was specifically informed by the FDA that the 1974 warnings were probably only "interim" pending the Advisory Committee meeting (T. 923; Plaintiff's Ex. 37, App. 511). Thus, Upjohn decided to limit promotion of the drug until the Advisory Committee met. The Advisory Committee did not meet until January of 1975 (App. 406).

E. *Dr. Carbo's Prescription of Cleocin for Plaintiff*

On December 10, 1974, Dr. Carbo, an opthalmologist who used antibiotics only five to ten times per year (App. 288), prescribed Cleocin for treatment of a chalazion on the plaintiff's eyelid (App. 287).

At this time, the revised warning was contained in the October 1974 supplement to the *Physicians Desk Reference* (PDR) to which Dr. Carbo subscribed, and the Supplement was admittedly received and available in his office (App. 299-300). Dr. Carbo had not read the 1974 warning in the PDR supplement or the "Dear Doctor" letter when he prescribed the drug to the plaintiff (App. 302), even though it was Dr. Carbo's regular practice, with respect to each of the very few drugs he used, to retain all "Dear Doctor" letters and attach them to the most current PDR for reference (App. 301). Thus, in prescribing Cleocin for the plaintiff, Dr. Carbo, by his choice alone,

relied totally on the information contained in the outdated 1973 package insert and on his own experience with the drug (App. 306). Dr. Carbo himself conceded that to review the 1974 warning in the PDR Supplement would have taken "only a minute" (App. 327).

Because Carbo had not read the "Dear Doctor" letter, he was not aware of Upjohn's estimate contained therein for incidence of "serious" colitis of 1 in 50,000 to 1 in 100,000 (App. 331). Thus, nothing in the "Dear Doctor" letter influenced Carbo's judgment to prescribe Cleocin for the plaintiff (App. 302).

F. *The 1975 Change in the Package Insert*

In January of 1975, the FDA Infectious Disease Advisory Committee met in Washington, D.C. As a result of those meetings and further dialogue between the FDA and Upjohn, a revised Cleocin package insert was prepared, approved by the FDA and published in March of 1975 (T. 944-45; Plaintiff's Exhibit 56-B, App. 581). It contained new warnings concerning the risk of colitis and PMC and revised indications for use of the drug. The major additions adopted by the 1975 warning were (1) a warning that antibiotic-induced colitis "may end fatally," and (2) an indication that Cleocin should be used only for "serious" infections. Similar package insert language had been the subject of discussion between Upjohn and the FDA in the summer of 1974 prior to the August 1974 change in the package insert. Upjohn moved *in limine* to exclude all reference to the 1975 warning, based on Rule 407 of the Federal Rules of Evidence (App. 43). The motion was denied (App. 53), and the 1975 warning was subsequently admitted into evidence, over Upjohn's objection (App. 138), for the alleged purpose of showing the "feasibility" of Upjohn providing the 1975 precautionary measures in 1974 (App. 465). However, the 1975 warning was used repeatedly by the plaintiff in the examination of expert witnesses and in argument to prove what plaintiff contended the 1974 warning "should have" said (*e.g.*, App. 140, 145-46, 174, 202, 454-55).

G. *The Testimony of the Experts*

Plaintiff's principal expert witness was Dr. Tedesco, who had conducted the 1974 Upjohn-sponsored study discussed above. After explaining his study and its results, he criticized the statements in the "Dear Doctor" letter as being nonrepresentative of the true incidence of serious colitis (App. 190). Tedesco conceded, however, that this judgment depended on how "serious" was defined (App. 189) and that if "serious" meant "resulting in death," then Upjohn's incidence figures would be realistic (App. 226). Tedesco never contended that his incidence figures should have been published. Tedesco further conceded that the 1974 revision substantially followed his recommendations for disclosure to the medical profession (App. 216-17, 240) and that the August 1974 package insert warned against the very side effects experienced by the plaintiff (App. 240-41, 217). Dr. Tedesco commented generally upon numerous other post-Tedesco studies which showed a much lower incidence of diarrhea and colitis (T. 494-511, 515-18, 516-28). The sum and substance of Dr. Tedesco's criticism of the 1974 warning was specifically that a warning of possible fatality should have been included and generally that the March 1975 warning should have been given in August 1974 (App. 202).

Dr. Richard Hornick, Professor Medicine and head of the Division of Infectious Diseases at the University of Maryland Medical School (App. 340-41) and Dr. Frank Calia, Professor of Medicine and Infectious Diseases at the University of Maryland Medical School (T. 1022) and Chief of Medicine at the Veteran's Administration Hospital (T. 1023), testified as expert witnesses on behalf of Upjohn. Dr. Hornick had previously served as a member of the FDA Antibiotic Advisory Board (App. 366). Both Dr. Calia and Dr. Hornick were thoroughly familiar with the drug, its uses, and adverse reactions (App. 341; T. 1024-26). Dr. Hornick and Dr. Calia each stated that the 1974 package insert was adequate to advise a reasonably competent physican of the adverse reactions and side effects from the use of Cleocin (T. 349-50, 435). Calia further testified that he believed it proper not to disclose the results of Dr. Tedesco's study either in the package insert

or in the "Dear Doctor" letter in August of 1974; Calia felt that such action would have been misleading (App. 437-38). Dr. Hornick discussed the existence of the other available data at the time of Tedesco's April 1974 report, which data indicated a much lower incidence of colitis and PMC than Tedesco found (App. 305-51, 375). Hornick also discussed numerous post-Tedesco studies that similarly reported much lower incidence figures (T. 801-02, 803, 816-20, 856-57). Hornick noted the wide variance in incidence figures between different geographical locations and different hospital environments (App. 351). Hornick personally knew of only one case of PMC after widespread use of Cleocin at University Hospital in Baltimore and knew of only one other in the entire metropolitan Baltimore community (App. 352). Hornick was also familiar with recent studies done by Dr. Francis Milligan at Johns Hopkins Hospital in Baltimore, which found a PMC incidence of only 0.3 percent (App. 353-54, 356-57, 816-17). Dr. Calia testified that serious colitis caused by Cleocin is a rare phenomenon with an incidence much lower than the incidence of pseudomembranous colitis (App. 435).

H. *Closing Argument, Instructions, Verdict, and Post-Trial Proceedings*

Following the denial of Upjohn's motion for directed verdict at the close of the evidence (App. 451), the case was argued to the jury and submitted under the court's instructions by way of special interrogatories (App. 51-52). Defendants excepted to the court's liability and damages instructions.

The jury requested further instruction on the strict liability issues (App. 491), and shortly after receiving further instructions the jury returned a special verdict for plaintiff on the issues of negligence and breach of warranty, but found in favor of Upjohn on the strict liability issue (App. 51). Damages of $400,000 were assessed (App. 52).

ARGUMENT

I.

BECAUSE THE BASIS OF THE FOURTH CIRCUIT'S REVERSAL WAS A HOLDING THAT THE

TRIAL COURT ERRED IN PERMITTING THE PLAINTIFF TO USE THE EVIDENCE OF THE SUBSEQUENT WARNING FOR THE SOLE PURPOSE OF PROVING CULPABLE CONDUCT ON THE PART OF THE DEFENDANT, CONTRARY TO THE PROVISIONS OF RULE 407 OF THE FEDERAL RULES OF EVIDENCE, WITH AN ALTERNATIVE HOLDING THAT THE JURY'S VERDICTS AS TO NEGLIGENCE AND STRICT LIABILITY WERE INCONSISTENT, AND BECAUSE THE FOURTH CIRCUIT'S VIEW ON THE INADMISSIBILITY OF THE SUBSEQUENT WARNING ON OTHER ISSUES WAS MERE DICTA OFFERED SOLELY FOR GUIDANCE UPON RETRIAL IN THE INTERESTS OF TIME AND JUDICIAL ECONOMY, THERE IS NO IMPORTANT ISSUE OF FEDERAL LAW WHICH IS RIPE FOR REVIEW AND SETTLEMENT BY THIS COURT OR WHICH IS IN CONFLICT WITH THE DECISION OF ANY OTHER CIRCUIT.

In his Petition for Writ of Certiorari, the plaintiff broadly asserts that the Fourth Circuit made rulings concerning the admissibility of evidence of subsequent remedial measures which the plaintiff contends are in conflict with decisions of other federal circuit courts of appeals. The plaintiff buries in his petition, however, the primary issue which had been raised by the defendant in the Court of Appeals and which formed the real basis for the Fourth Circuit's reversal and remand for a new trial: Whether the trial court erred in permitting the plaintiff to use the evidence of the subsequent warning for the sole purpose of proving negligence and culpable conduct on the part of the defendant, contrary to the express provisions of Rule 407 of the Federal Rules of Evidence, particularly where the evidence had been offered and admitted solely for the purpose of proving the feasibility of giving the warning at an earlier date. Plaintiff also conveniently ignores the express doubts indicated in the Fourth Circuit's opinion as to whether the issue of the admissibility of the evidence for other purposes was even properly before it because the issue was not raised at

trial and the further express indication of the Fourth Circuit that it only examined that issue "because this case must be tried again," obviously in the interests of time and judicial economy. Under such circumstances the plaintiff is simply wrong in his conclusion that an important, unsettled question of federal law was decided and that this "decision" was in conflict with any other circuit. Rather, the Fourth Circuit's ruling in this case was narrowly based upon the application of the clear and unambiguous language of Rule 407, which prohibits the admission and use of evidence of subsequent remedial measures to prove negligence or culpable conduct on the part of the defendant.

The holding of the Fourth Circuit that a new trial was required because the trial court improperly permitted the plaintiff to use evidence of the subsequent warning to prove culpable conduct, contrary to the provisions of Rule 407 of the Federal Rules of Evidence, was succinctly stated in the written opinion of the Court of Appeals:

> Federal Rule of Evidence 407, which enacts the common law rule excluding subsequent remedial measures to prove negligence, does, however, permit evidence of subsequent remedial measures to be used to prove the feasibility of such measures, but only if feasibility is controverted by the defendant. But, despite the judge's limiting instruction on this point it is clear that the 1975 warning was used by the plaintiff to prove negligence. The warning was mentioned several times during the course of the trial when expert witnesses were asked whether the information in the 1975 warning should have been included in the 1974 warning if that information had been available to Upjohn at the time the 1974 warning was given. This use of the warning has no conceivable connection to feasibility. The plaintiff's expert witnesses were asked time after time whether Upjohn "should have" included the information in the 1975 warning in the 1974 warning. The obvious inference is that if Upjohn should have used the subsequent warning earlier, then it was negligent for failing to do what it "should have" done. This use of the 1975

> warning clearly was impermissible and constitutes reversible error. *Columbia & Puget Sound R. Co. v. Hawthorne*, 144 U.S. 202 (1892).

(P. App. 6a-7a.) The holding of the Fourth Circuit, therefore, was much more limited in its effect than represented by plaintiff. There can be no question that the true basis of the Fourth Circuit's ruling was that regardless of any arguments advanced by plaintiff in support of the admissibility into evidence of the subsequent warning, it was the use of such evidence by plaintiff's counsel to prove negligence and culpable conduct on the part of defendant which required reversal of the judgment of the District Court. In short, it is clear from the opinion of the Fourth Circuit that reversal would have been required solely because of the improper use of the evidence by plaintiff's counsel.

The Fourth Circuit's decision was also based on a clear alternative ground, which the plaintiff concedes is not a proper issue for review by way of certiorari. The Fourth Circuit stated:

> One further point deserves specific mention for it serves as an alternative ground for a new trial for Upjohn. It is claimed that the verdict for Upjohn on the issue of strict liability is inconsistent with the verdict against Upjohn on the issue of negligence. We agree. The effect of the jury verdict on negligence was to find that Upjohn failed to use due care to give an adequate warning of the propensities of the drug marketed, and, in the same breath, the verdict on strict liability found that the drug marketed with such an inadequate warning was not unreasonably dangerous. The verdicts in the context of this failure to warn case involving prescription drugs are obviously inconsistent and cannot stand. The same may be said of the verdict against Upjohn so far as it may be upon an implied warranty, for the only evidence that the drug was not reasonably fit concerned the warning.

(P. App. 19a-20a.) This holding is undoubtedly correct.

By special verdict on the negligence issue, the jury found that the defendant Upjohn failed to exercise reasonable care to give an adequate warning to the medical profession of the risks of Cleocin and that this failure was a proximate cause of

the plaintiff's injury. The jury further found, however, that Upjohn did not market or sell Cleocin in a defective condition unreasonably dangerous to the consumer proximately resulting in injury to the plaintiff, and under the Court's instructions, this finding necessarily indicates that the jury found the warning adequate or that any inadequate warning was not a proximate cause of the plaintiff's injury. Thus, the special finding in favor of Upjohn on the strict liability issue is directly contrary to the jury's findings against Upjohn as to negligence. This inconsistency necessitated the granting of a new trial by the Fourth Circuit.

The law is settled that the inconsistency of a jury's verdict is grounds for a new trial under Rule 59(a) of the Federal Rules of Civil Procedure. *6A Moore's Federal Practice* ¶ 59.08[4], at 59-141 (2d ed. 1979). Indeed, where the verdicts in the same case are patently inconsistent, indicating that the jury was confused or had abused its power, there is no discretion in the trial court on the Rule 59 motion—a new trial must be granted. *Hopkins v. Coen*, 431 F.2d 1055, 1059 (6th Cir. 1970); *Global Van Lines v. Nebeker*, 541 F.2d 865, 868 (10th Cir. 1976); *Wood v. Holiday Inns, Inc.*, 508 F.2d 167, 175 (5th Cir. 1975). Moreover, the court has a positive duty to grant the new trial where the verdict manifests that the jury has not followed the Court's instructions. *Magill v. Westinghouse Elec. Corp.*, 464 F.2d 294, 301 (3rd Cir. 1972); *Reisberg v. Walters*, 111 F.2d 595, 597 (6th Cir. 1940); *6A Moore's Federal Practice* ¶ 59.08[4], at 59-139 (2d ed. 1979).

In this case, under the law and under the trial court's instructions, the verdicts of the jury are inconsistent and irreconcilable. Setting aside the narrow question of whether there is any difference between negligence and strict liability in tort with respect to the duty of a prescription drug manufacturer, it is clear that if a difference does exist under general products liability law, the manufacturer's duty in strict liability is broader than that in negligence, since theoretically one could market a defective product, but not be negligent in doing so. *See Chestnut v. Ford Motor Co.*, 445 F.2d 967, 969 (4th Cir. 1971). A finding in favor of the manufacturer on strict liability therefore necessitates the same disposition on negligence, since

implicit in such a finding is the absence of a defect or unreasonably dangerous condition in the product proximately causing the plaintiff's injury. *See Caplaco One, Inc. v. Amerex Corp.*, 435 F. Supp. 1116, 1120 (E.D. Mo. 1977). Thus, a verdict in favor of a manufacturer in strict liability, but against the manufacturer in negligence, is logically inconsistent. *Halvorson v. American Hoist & Derrick Co.*, 240 N.W.2d 303, 307 (Minn. 1976).

The same reasoning obviously applies under the law relating to a drug manufacturer's duty to warn. Under the law, if a drug manufacturer negligently fails to warn of the side effects of a drug of which the manufacturer knows or should know, it is liable also in strict liability for the failure to warn, since the absence of the adequate warning renders the drug "defective and unreasonably dangerous" within the meaning of Section 402A of the *Restatement*. On the other hand, if a drug manufacturer is not liable in strict liability, i.e., the drug was not defective because an adequate warning was given, *Restatement (Second) of Torts* §402A, comment *k*, then neither can the manufacturer be held negligent for selling an unavoidably unsafe drug, but with an adequate warning. *See Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 425-427 (2nd Cir. 1969). Thus, under the law, the jury's finding in favor of Upjohn on the strict liability issue–*which necessarily included a determination that Upjohn's warning was adequate or that any inadequacy was not a proximate cause of the injury*–was hopelessly inconsistent with the jury's verdict for the plaintiff on the negligence issue, with the specific finding that the warning was *not* adequate and that such negligence *was* a proximate cause of the plaintiff's injury.

The Fourth Circuit was thus correct in basing its reversal on this clear alternative ground, which Petitioner concedes is not a proper certiorari issue.

In his Petition for Writ of Certiorari, however, the plaintiff represents to this Court that the real reason for the Fourth Circuit's reversal was its ruling that, in the context of this case, the evidence of the subsequent warning would not be admissible on the issues of strict liability, breach of warranty, causation, and feasibility. From the written opinion of the Fourth Circuit itself, however, it is clear that its rulings in this regard were not

grounds for reversal, but rather, were merely dicta to offer guidance to the District Court on retrial, in the interests of time and judicial economy. Indeed, the Fourth Circuit expressed its doubts that those questions were even before it, since they were not squarely raised below.[2] Specifically, the Fourth Circuit stated:

> Alternatively, plaintiff argues that even if the 1975 warning was not admissible to show feasibility it was admissible on other grounds. It is arguable that this question is not directly before us on appeal because the 1975 warning was in fact used to prove negligence, and *thus the fact that the evidence might have been admissible on some other ground not raised at trial should not prevent reversal and a new trial. Especially because this case must be tried again*, and we do not believe that the 1975 warning was admissible, we examine plaintiff's other arguments for admitting the evidence.

(P. App. 11a, emphasis added.) Thus, the main issue pressed by the plaintiff in his Petition for Writ of Certiorari was dealt with by way of dicta by the Court of Appeals below and was not the basis for its decision. Rather, the issue was discussed by the Fourth Circuit only for guidance on retrial in the interests of time and judicial economy, and was not even squarely before the Fourth Circuit for decision. Accordingly, the main issue presented by the plaintiff to this Court is not ripe for review, and the Fourth Circuit therefore has not actually decided an important question of federal law which should be decided or settled by this Court.

Moreover, because the actual basis for the Fourth Circuit's ruling is other than as plaintiff contends, it is apparent that the decision of the Fourth Circuit cannot be squarely in

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[2]In its instructions, the trial court limited the use of the evidence of the subsequent warning to the issue of feasibility (P. App. 6a). Plaintiffs did not except to this instruction or even request an instruction broadening the use of the evidence to the issues of strict liability, warranty, or causation. Accordingly, plaintiffs were not in any position to raise other grounds for admissibility on appeal.

conflict with the decision of the Eighth Circuit in *Robbins v. Farmers Union Grain Terminal Ass'n*, 552 F.2d 788 (8th Cir. 1977). First, unlike the Fourth Circuit's opinion in this case, the *Robbins* court did not base its decision on the improper use of the evidence of subsequent remedial measures at trial, and specifically found it unnecessary to do so. *Id.* at 792. Second, in *Robbins*, the trial court gave no limiting instruction, and the defendant did not request one, nor did it object to the court's failure to give a limiting instruction. The opposite is true in this case. Finally, the issue of the use of the evidence for strict liability purposes was squarely before the *Robbins* court, since the lower court had ruled it admissible for that purpose. *Id.* In this case, however, it was not before the Fourth Circuit, because the plaintiff simply failed to preserve the point during trial by not objecting to the trial court's instruction limiting the use of the evidence to the issue of feasibility only.

In short, the Fourth Circuit's decision below was based on two clear alternative grounds: (1) that a new trial was required because the trial court erred in permitting the plaintiff to use the evidence of the subsequent warning to show negligence and culpable conduct of the defendant; and (2) that the jury verdicts in favor of the defendant on the strict liability issue and against the defendant on the negligence issue are irreconcilably inconsistent. The first ground is a settled application of Rule 407 under its clear and unambiguous provisions. The second ground is concededly not a proper issue for review by this Court by way of certiorari. Accordingly, this case presents no important issue of unsettled federal law actually decided by the Fourth Circuit which is necessary or desirable for this Court to review. That the Fourth Circuit addressed the issues raised in plaintiff's Petition for purposes of guidance to the trial court on retrial in the interests of time and judicial economy does not present a ripe or justiciable issue for decision by this Court, particularly in light of the fact that plaintiff clearly failed at trial to preserve his issues for appellate review, even by the Court of Appeals. These factors show equally that there has been no actual decision by the Fourth Circuit of important federal law which conflicts with the decisions of the Court of Appeals of any other circuit, since the alternative bases for the Fourth Circuit's

opinion was never addressed in the *Robbins* decision of the Eighth Circuit, even by way of dicta. Accordingly, the plaintiff's contentions in support of his petition for review of the case by way of certiorari are totally without merit, and the Petition for Writ of Certiorari should therefore be denied.

II.

THE DICTA OF THE COURT OF APPEALS RELATING TO THE INADMISSIBILITY OF THE EVIDENCE OF THE SUBSEQUENT WARNING, WHICH WAS GIVEN FOR GUIDANCE TO THE DISTRICT COURT ON RETRIAL, IS NOT IN CONFLICT WITH THE DECISION OF THE EIGHTH CIRCUIT IN *ROBBINS*, SINCE THE TWO CASES ARE CLEARLY DISTINGUISHABLE AND RECONCILABLE BOTH FACTUALLY AND LEGALLY.

A. *The Fourth Circuit correctly stated that in the context of this drug liability case, where the sole issue is the adequacy of the warning, evidence of a subsequent warning is inadmissible on the issues of strict liability and breach of warranty, and this statement is not in conflict with the Eighth Circuit's decision in Robbins.*

The Fourth Circuit correctly stated that in a drug liability case where the sole issue is the adequacy of the warning of side effects because the drug is an unavoidably unsafe product within the meaning of comment *k* of Section 402A of the *Restatement (Second) of Torts*, issues of negligence, strict liability and breach of warranty are the same, and all involve proof of culpable conduct. Thus, in the context of this case, where the adequacy of the warning is the sole issue, evidence of the subsequent warning is not admissible on the strict liability and warranty issues because such proof would be in violation of the express provision in Rule 407 that "evidence of the subsequent measures is not admissible to prove negligence or culpable conduct in connection with the event." The Fourth

Circuit noted that the rule itself does not speak in terms to the question of whether the evidence should come in to prove strict liability or breach or warranty (App. 13a). In the context of the issues raised by the record in this case in the trial court, however, no distinction could be made between the issues of negligence, strict liability, or breach of warranty (App. 15a-17a). The court expressly noted:

> . . .Under a negligence theory the issue is whether the defendant exercised due care in formulating and updating the warning, while under a strict liability theory the issue is whether the lack of a proper warning made the product unreasonably dangerous. Though phrased differently the issue under either theory is essentially the same: was the warning adequate?. . .
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> Any remaining distinction in theories disappears when a failure to warn case involves an unavoidably dangerous drug which the product in this case admittedly was. The Restatement of Torts (2d) §402A, comment k makes it clear that a drug manufacturer is not to be held strictly liable for injuries caused by an unavoidably dangerous new drug if the warning is adequate. The standard for liability under strict liability and negligence is essentially the same. *Chambers, supra* at 381.
>
> Since the issue under either theory is the same, a decision which admits evidence of subsequent remedial measures on a strict liability theory in a failure to warn case involving an unavoidably dangerous drug would promote substance over form and subvert the policy behind excluding evidence of subsequent remedial measures. We decline the invitation to follow the other courts which may have so held, and prefer the reasoning of *Chambers v. G. D. Searle & Co.*, 441 F.Supp. 377 (D.Md. 1975), exactly to the point here, and *Smith v. E. R. Squibb & Sons, Inc.*, 273 N.E.2d 476 (Mich. 1979), very nearly so.

(P. App. 16a-17a.)

The effect of the Fourth Circuit's language is that where the issue in the trial court focuses entirely on the reasonableness

of the defendant's conduct in giving a warning in light of knowledge existing at the time of the ingestion of the drug, the analysis of the defendant's conduct by the trier of the fact to establish a violation of a duty owed by defendant to the plaintiff necessarily involves proof of that type of culpable conduct expressly forbidden by Rule 407. The opinion does not foreclose admission into evidence of subsequent remedial measures when offered to prove that the product was unreasonably dangerous and defective under a different kind of strict liability case.

The Eighth Circuit's decision in *Robbins* is not in conflict with the Fourth Circuit's opinion here, because the two cases arose in a vastly different factual context and involved the application of conflicting local law. Even under the Federal Rules of Evidence, a federal court sitting in diversity must first determine whether the proffered evidence is material and legally relevant to the substantive issues of state law to be decided. The state law of strict liability involved in *Robbins*, however, differed substantially from the law of Maryland involved in this case. The *Robbins* case involved the adequacy of warnings and instructions for use accompanying the defendant's cattle feed, which cannot be deemed an "unavoidably unsafe" product within the meaning of comment *k* of Section 402A of the *Restatement*. The Eighth Circuit specifically noted that knowledge of the defendant was *not* an element of a strict liability action under the state law there applicable; rather, that the law imputed knowledge to a manufacturer of the harmful character of its product, whether it actually knows of it or not. *Id.* at 794-95, n.15. Thus, the *Robbins* court held that the local strict liability law did not involve "culpable conduct," and thus, the subsequent warning was relevant to show that the product was dangerous and defective because of an inadequate warning and to show that safer design or warning was feasible. *Id.* The substantive strict liability law applicable to the instant case, however, is contrary to that in *Robbins*. Unlike *Robbins*, the instant action is a drug liability case involving an unavoidably unsafe product within the meaning of comment *k* of Section 402A of the *Restatement*. Under that comment, the theory of strict liability as far as drugs are concerned is essentially the same as the theory of negligence, where the sole

question is the adequacy of the warnings accompanying the drug. *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377, 380 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977). Negligence principles are therefore fully applicable even to the strict liability claim. *Id.*; Merrill, *Compensation for Prescription Drug Injuries*, 59 Va. L. Rev. 1, 31 (1973); *see Nolan v. Dillon*, 261 Md. 516, 523, 276 A.2d 36, 40 (1971). Unlike *Robbins*, the knowledge of the manufacturer in this case was clearly relevant to the strict liability issues.

Moreover, an "adequacy of warning" case is nothing more than one involving "defective design," to which strict liability is not applicable under Maryland law, but rather traditional principles of negligence apply, *Frericks v. General Motors Corp.*, 274 Md. 288, 336 A.2d 118 (1975), except under limited circumstances where the conditions are so obviously dangerous that, whether caused by errors in design or manufacture, they can never be said to involve a reasonable risk. *Phipps v. General Motors Corp.*, 278 Md. 337, 345, 363 A.2d 955, 959 (1976). This principle is fully applicable to drug cases under Maryland law. *Nolan v. Dillon*, 261 Md. 516, 276 A.2d 36 (1971). Maryland law thus provides that a manufacturer is not to be held liable unless, after a traditional balancing of "utility-risk" as is done in negligence cases, the trier of facts finds that the conduct of the manufacturer was indeed unreasonable. As contrasted to the law of the jurisdiction applicable in the *Robbins* case, Maryland law on strict liability in an "adequacy of warning" case *does* involve all of the elements of culpable conduct recognized in *Chambers v. G.D. Searle & Co., supra*.

In short, the decisions of the Eighth Circuit in *Robbins* and of the Fourth Circuit in this case are quite distinguishable solely on the basis of the local law of strict liability, which clearly affect each court's application of Rule 407 of the Federal Rules of Evidence. Indeed, the two decisions can be reconciled on this basis. While the evidence may have been admissible in *Robbins* because it was relevant to establish a "defect" in the product in the absence of "culpable conduct" on the part of the manufacturer, it could not be so admitted on the strict liability issue in this case, because Maryland law does not permit recovery in a drug case involving adequacy of warning on the

basis of strict liability unless the plaintiff shows some antecedent knowledge on the part of the manufacturer which would render its conduct unreasonable and culpable under the same standards applicable in negligence cases. How the Fourth Circuit would rule under the *Robbins* factual circumstances with different principles of local law to be applied is unknown and cannot be derived from its opinion in this case. Simply stated, any "conflict" in the two cases was mandated only by the difference in local law of products liability which was applied by each court under entirely different and distinct factual circumstances.

Accordingly, contrary to the plaintiff's contention in his Petition, the Fourth Circuit's opinion in this case is not in conflict with any other circuit on the applicability, scope, interpretation and administration of Rule 407. Because of the different applicable local law and the distinct factual circumstances in each case, the two decisions do not present such a conflict as to require this Court to attempt to achieve a uniform result in the two distinct factual and legal settings. Indeed, because of the great factual and legal differences in the two cases, any such attempt to establish a hard-and-fast, uniform rule would be undesirable and contrary to the purpose of the Federal Rules of Evidence to promote growth and development of the law of evidence and to secure fairness in the administration of justice on a case-by-case basis. *See* Fed. R. Evid. 102.

B. *The Fourth Circuit correctly stated that the evidence of the subsequent warning did not become admissible under Rule 407 merely because the subsequent warning was required by the Food and Drug Administration. This statement is not in conflict with any decisions of other Circuit Courts of Appeals.*

In asserting that the Fourth Circuit erroneously found that the evidence of the subsequent warning was not admissible merely because it was required by the FDA, plaintiff ignores the particular and compelling policy reasons for inadmissibility noted by the Fourth Circuit under the FDA regulatory scheme, which were not involved or discussed in the other cases cited by the plaintiff in his Petition. Plaintiff also overlooks the principle that Rule 407 governs admissibility of *admissions by conduct*,

which obviously cannot apply where the particular action taken was not voluntary, but rather was required by a third-party, since the theory of an "admission" is no longer available. *McCormick On Evidence* §275, at 667 n. 17 (2d ed. 1972).

The Fourth Circuit succinctly responded to the plaintiff's argument that the evidence was admissible merely because the FDA required the subsequent warning:

> Plaintiff's final argument on the admissibility of the 1975 warning is that it was required by the FDA, and that since defendant Upjohn had no choice in the matter, the policy behind Rule 407 would not be served by excluding the evidence. While this argument may have a surface plausibility, we do not believe the evidence should be admitted for this reason. First, when a third party has required the change the relevance of the evidence is one more step removed from the central issue in the case, the adequacy of the warning at the time the product was marketed. When a third party makes a subsequent change the inference is removed not only in time but in who made the change. This is especially true in the case at bar since the FDA itself approved the 1974 warning at the time it was first used. Thus, it would appear that any separate relevance of the FDA's actions with regard to the 1975 warning is overridden by the fact that the FDA approved the 1974 warning as well.
>
> Furthermore, plaintiff's argument overlooks the dual responsibility for preparing warnings for prescription drugs. The FDA can require that a warning be changed, but this does not tell the whole story. In addition to its broad regulatory sanctions it is clear that it also relies on voluntary compliance and compromise in determining the content of warnings and advertising for prescription drugs. See Dixon, Drug Product Liability §5.05. This cooperative aspect of prescription drug regulation is apparent in the correspondence between Upjohn and FDA in the case at bar in arriving at warnings and their changes. Furthermore, FDA regulations allow drug companies to change the labels

> and warnings accompanying their products without prior FDA approval where new side effects are discovered by the company. 21 C.F.R. §314.8(d)-(e).
>
> The. . .regulations demonstrate that plaintiff's argument is without merit. If subsequent warnings are admitted to prove antecedent negligence simply because FDA required or might have required the change, then drug companies may be discouraged from taking early action on their own and from participating fully in voluntary compliance procedures. Thus, we think that the FDA's regulatory power should not be read as in conflict with the protective policy of Rule 407. The FDA's regulations and policies encourage early unilateral action by the drug companies to improve their warnings, and Rule 407 promotes the same goal. We therefore hold that FDA regulations in the area of drug labeling do not require a new exception to Rule 407. Indeed, to find such an exception would subvert the policy goals of both Rule 407 and FDA Regulations 314.8(d)-(e).

(P. App. 17a-19a.)

It was because of the factual context in which the subsequent warning was given in this case in cooperation with the FDA, and that all of the matters addressed in a subsequent warning were the subject of discussion between Upjohn and the FDA in the summer of 1974 prior to the August 1974 change in the package insert, that the admission of the evidence was precluded. This is not a case where the regulatory agency based on information not revealed by defendant required a subsequent warning, but it is simply a case where the regulatory agency, in cooperation with the manufacturer, approved a different warning after the date of the event giving rise to the lawsuit not based on any new information not previously disclosed by the defendant but only as a result of a meeting of the FDA Infectious Disease Advisory Committee and further dialogue between the FDA and Upjohn (T. 944-45; Plaintiff's Exhibit 56B, App. 581).

These particular facts and policy considerations were simply not present in the cases cited by the plaintiff which

purportedly are in conflict with the Fourth Circuit's opinion in this case, and in two of the cases, the pronouncements were merely dicta. In *Rozier v. Ford Motor Co.*, 573 F.2d 1332 (5th Cir. 1978), the admissibility of a "Trend Cost Estimate" was at issue. The Fifth Circuit expressly found that the document was *not* prepared by the defendant *after* the "event" in question, and that the document was not a "remedial measure taken." *Id.* at 1343. The Fifth Circuit also expressly found the document admissible on other issues. *Id.* The Fifth Circuit's statements in connection with Rule 407 were therefore pure dicta. In *Farner v. Paccar, Inc.*, 562 F.2d 518 (8th Cir. 1977), the second case cited by the plaintiff, the Eighth Circuit's statements with respect to the safety measures carried out by a third-party were stated as dicta in a footnote and were far from a direct holding that such evidence would be admissible in *all* cases. *Id.* at 528, n.20 ("We also note that the rule against admission of subsequent remedial measures in negligence cases *may* not apply in any event since the corrective measures were not carried out by the defendant.") (emphasis added). Finally, *Lolie v. Ohio Brass Co.*, 502 F.2d 741 (7th Cir. 1974), the third case cited by plaintiff, was decided prior to the effective date of the Federal Rules and merely held without discussion that remedial measures taken at the direction of the state mine inspector were admissible. *Lolie* was not a drug liability case, and the compelling policy considerations under the FDA regulatory scheme were not discussed or involved.

In short, an analysis of the cases cited by the plaintiff in "conflict" with the dicta of the Fourth Circuit in this case reveals no actual decision in which the same issues were raised or in which actual conflicting rulings were made. At best, the cases provide merely conflicting dicta in widely different factual contexts, but offer no direct conflict which is necessary or desirable for this Court to resolve. To do so would require this Court to lay down broad, hard-and-fast rules which would prevent the flexibility and liberality that the Federal Rules of Evidence are designed to achieve on a case-by-case basis.

Regardless of any alleged conflict among the circuits on this issue, however, the plaintiff misconceives the applicability of Rule 407 in the context of remedial actions taken by third parties. Rule 407 is based upon the theory that certain types

of conduct on the part of the defendant may be used as implied "admissions." Advisory Committee's Note Rule 407; 2 *Weinstein's Evidence* ¶407 [01], at 407-5 (1980). Rule 407 does not set forth a broad rule of admissibility of such conduct when offered for purposes other than negligence or culpable conduct. Rather, the rule merely states that it "does not require exclusion" of the subsequent remedial measures when offered for other purposes. Nevertheless, the evidence must be relevant and admissible for some purpose before any question as to the applicability of Rule 407 is presented, and the general rules governing relevancy apply to subsequent remedial measures made or ordered by a third party. 2 *Weinstein's Evidence, supra* at 407-7; Fed. R. Evid. 401-3.

When evidence of subsequent remedial measures made or required by third parties is offered, however, there no longer exists a theory that such evidence is admissible as an "admission" of a party, because an admission by the *defendant's* conduct as to a relevant issue can no longer be implied. *McCormick on Evidence* §275, at 667 n. 17 (2d ed. 1972). Rather, when the remedial measures are made or ordered by a third party, such evidence is actually a hearsay statement of opinion by such third party, who is not present in court for cross-examination. *Id.*; see Fed. R. Evid. 701, 801 (c) - (d).

Clearly, the plaintiff in this case could not have used as evidence an unsworn, out-of-court statement from a FDA official stating that in his opinion, a stronger warning should have been given. Such evidence would not only constitute hearsay, but also inadmissible opinion evidence. Yet, the effect of the admission of the subsequent warning required by the FDA would be the same, for it is clearly an implied, unsworn statement of opinion of a FDA official that the later warning should have been given earlier. Admission of such an implied statement would deprive the defendant of the right to cross-examine that statement, and, particularly with reference to this case, to point out that the same individual had previously believed, based upon the same state of his knowledge, that the earlier warning was adequate. It was clearly not the intent of Rule 407 to open the door to such hearsay opinion evidence. Rather, the design of the rule is to exclude on policy grounds certain evidence that would otherwise satisfy the Federal Rules'

requirements of relevancy, competency and admissibility. Under such circumstances, the fact that the FDA required the subsequent warning renders the evidence inadmissible for any purpose and hardly brings the evidence within an "exception" to Rule 407.

C. *The Fourth Circuit correctly stated that evidence of a subsequent warning is not admissible as evidence of the feasibility of giving a warning different from that actually given, where such feasibility was not in fact controverted by Upjohn. This statement is not in conflict with the decision of the Court of Appeals of another circuit.*

Although petitioner strives mightily to indicate that feasibility was in fact controverted, the opinion of the Fourth Circuit puts any such argument to rest by its succinct observations in the opinion:

> Plaintiff's position is further weakened by the fact that the feasibility of giving the 1975 warning in 1974 simply was not in issue in the case. As stated above, Rule 407 does allow evidence of subsequent remedial measures to be used to prove the feasibility of such measures, but only if feasibility is controverted by the defendant. The Advisory Committee Notes to Rule 407 state in terms that "unless a genuine issue" of feasibility is present the exception should not apply. The plaintiff contends that the issue of feasibility was controverted sufficiently to invoke the exception. His first argument is that no concession was made by defendant on this issue. However, it is clear from the face of the rule that an affirmative concession is not required. Rather, feasibility is not in issue unless controverted by the defendant.
>
> In an effort to show a controverted issue of feasibility the plaintiff points to two statements Upjohn made to the FDA during negotiations on what was to be the exact content of the 1974 warning in which Upjohn purportedly argued that a stronger warning would be "misleading" or

would have a "potential for much harm." When these statements are examined in context it is apparent that plaintiff's argument is without merit. The first statement was made in reply to the FDA's suggestion that the phrase "and more rarely in PMC" be added to the 1974 warning. Upjohn's reply suggested a warning which stated: "Antibiotic associated 'PMC' can occur." In rejecting use of the word "rarely" Upjohn noted that Dr. Tedesco's study indicated that incidence was higher than "rarely" and that in general Upjohn preferred to avoid terms such as "rarely" or "infrequently", "since there is a distinct possibility of misleading". Thus, it appears that Upjohn's proposed exclusion of the word "rarely" strengthened, rather than weakened, the FDA's proposed warning, and certainly had nothing to do with controverting the feasibility of a stronger warning.

The second example cited by plaintiff arose out of an FDA request that the 1974 package insert include a warning that Cleocin not be used for minor infections. Such a warning ultimately was adopted in substance in the 1975 warning. In objecting to the FDA's proposal Upjohn stated that "there is no precise definition of minor or trivial infections and the physician is adequately guided by the limitation of the approved INDICATIONS. Such a statement has a potential for much harm and little or no benefit." The above quoted statement does not controvert the feasibility of writing a warning that Cleocin not be used for minor infections. It merely questions the necessity of such a warning. This distinction points up the basic position of Upjohn in this case that the 1974 warning was adequate. Upjohn does not argue that it could not have written a stronger warning, it argues that the 1974 warning was adequate given the knowledge it had at that time. This defense simply does not raise an issue of feasibility.

Thus, plaintiff's efforts to expand the feasibility exception must fail. Since feasibility was not in issue in the case the evidence should have been excluded. See Advisory Committee Notes to Rule 407.

(P. App. 9a-10a.)

Thus, the Fourth Circuit, after a thorough and conscientious review of the evidence as recorded in the record extract, expressly found that feasibility was not in issue in this case. The express language of Rule 407 states that evidence of a subsequent warning to prove feasibility is not admissible when feasibility is not controverted by the defendant. Accordingly, the evidence was not admissible on the feasibility issue.

The plaintiff claims, however, that this Court should review this dicta by the Fourth Circuit because it again "conflicts" with the Eighth Circuit's decision in *Robbins v. Farmers Union Grain Terminal Ass'n*, 552 F.2d 788 (8th Cir. 1977). This contention is without merit. In *Robbins*, the Eighth Circuit specifically did not reach the question because it found that the evidence was admissible on other grounds and that the defendant had failed to request any limiting instruction or object to the trial court's failure to give a limiting instruction. *Id.* at 792. Indeed, the Eighth Circuit even questioned the procedure used by the trial court in forcing the defendant either formally to admit feasibility or allow the evidence of the subsequent warning. *Id.* n. 8. Thus, there is simply no conflict between the dicta of the Eighth Circuit in *Robbins* and the dicta of the Fourth Circuit in this case that even approaches the satisfaction of any standard for desirable or necessary review by this Court. Under such circumstances, the Petition for Writ of Certiorari should be denied.

CONCLUSION

Because the opinion of the Fourth Circuit correctly addresses the issues in the factual context of this case, as demonstrated by the record from the United States District Court, the Petition for Writ of Certiorari should be denied. A perceived conflict between the opinion of the Fourth Circuit and the opinion of the Eighth Circuit Court of Appeals in *Robbins* is an erroneous perception by petitioner, and the difference in the results and dicta of the two cases is one that derives from a vastly different factual and legal context in which the evidence of subsequent warnings was offered. The Fourth Circuit correctly based its opinion on a judgment that

regardless of the admissibility *vel non* of the evidence of the subsequent warning, its improper use by counsel below required reversal, a ruling that involved a settled application of Rule 407 under its clear and unambiguous provisions. The Fourth Circuit also correctly based its reversal upon a judgment that the verdicts of the jury were irreconcilably inconsistent, which Petitioner concedes is not a proper certiorari issue. For these reasons, the Petition for Writ of Certiorari should be denied, and the judgment of the Court of Appeals for the Fourth Circuit should be left undisturbed.

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No. 80-680

FILED
DEC 4 1980
MICHAEL RODAK JR., CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1980

JACK WERNER,
Petitioner,

v.

THE UPJOHN COMPANY, INC. AND
RALPH J. CARBO, JR., M.D.,
Respondents,

PETITIONER'S REPLY BRIEF ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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December 4, 1980

The Daily Record Co., Baltimore, MD 21202

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ARGUMENT

I.

THIS CASE PRESENTS AN INTERCIRCUIT CONFLICT.

Respondents argue that the decision below is not in conflict with any other Federal circuit decisions concern-

ing Rule 407 of the Federal Rules of Evidence. This is somewhat surprising since the Fourth Circuit perceived the conflict: it pointed out that "the courts have split" on the applicability of Rule 407 in strict liability cases, and it cited *Robbins v. Farmers Union Grain Terminal Assn.*, 552 F.2d 788 (8th Cir. 1977) as a decision of one of the courts which "would admit the evidence" (P. App. A. p. 12a).

Respondents contend that the rulings of the Fourth Circuit are dicta because (a) they are merely for the guidance of the District Judge on retrial and (b) the Fourth Circuit expressed doubt as to whether the admissibility of the evidence on the grounds urged by Petitioner were properly before it. The Fourth Circuit, however, has stated its holding: "We *hold* that the district court erred *in admitting the subsequent warning into evidence.*" (P. App. A. p. 2a, Emphasis supplied). Moreover, since the verdict was in Petitioner's favor on several special interrogatories (App. 51-2) the Fourth Circuit had to and did consider the various grounds for admissibility raised by Petitioner in order to hold that any possible error in admitting the evidence was not harmless.[1]

The decision of the Fourth Circuit is binding on the district judge on retrial and will foreclose petitioner from offering the evidence of the subsequent warning on any ground. The Fourth Circuit decision has as much "bite," and is as ripe for review by this court, as a ruling on evidence can be; and it should be reviewed in order to

[1] Thus, the jury found for plaintiff on the express warranty issue. This finding is independent of any issue of negligence or culpable conduct, and if the evidence of the subsequent warning was admissible to prove breach of warranty (Petition pp. 23-4), the decision below is wrong. Respondents simply do not — because, it is submitted, they cannot — address petitioner's argument on this point.

prevent the injustice which will occur in civil trials in that Circuit if, as Petitioner contends, the decision is wrong.[2]

The decision, moreover, is no less a holding because it also rested on an "alternate ground" of alleged inconsistency of verdict. It is well settled that when a decision is explicitly rested on alternate grounds,[3] both grounds are holding and neither is dictum. *Woods v. Interstate Realty Co.*, 337 U.S. 535 (1948); *Richmond Screw Anchor Co. v. U.S.*, 275 U.S. 531 (1928); *U.S. v. Title Ins. & Trust Co.*, 265 U.S. 472 (1924).

Respondents contend that the Fourth Circuit felt it was "arguable" that the possible admissibility of the evidence on grounds not raised at trial (Resp. Upjohn Br. p. 16) would not prevent reversal. The simple answer is that the Fourth Circuit's doubts did not prevent it from "examining" "plaintiff's other arguments for admitting the evidence" (P. App. 11 a) and holding the evidence inadmissible on any ground. Furthermore, it has been settled for well over a century that where the judgment of the trial court was in favor of Petitioner, that judgment may be supported on appeal upon any ground apparent from the

[2] Respondent Carbo seems to think there is no lack of ripeness for review since he asks that the writ of certiorari issue so that the judgment and opinion below may be affirmed. The petition for certiorari, of course, was not a definitive brief on the merits, but merely an attempt to show that the questions presented are substantial and should receive plenary review.

[3] Respondents simply do not, again because, it is submitted, they cannot, point to any error or fallacy in Petitioner's demonstration that the verdicts on the negligence and strict liability issues are fully consistent (Petition pp. 11-12, 27 n.11). The very recent case of *Hasson v. Ford Motor Co.*, 19 Cal. 3d 530, 138 Cal. Reptr. 705, 564 P.2d 857 (1980) also supports Petitioner's argument on this point. The court held that there was no inconsistency between a verdict for a manufacturer on strict liability where at the time of sale the product was deemed not defective and against the manufacturer for negligence in failing to warn after the sale.

record which renders it correct, whether that ground was relied on at trial or not. See *California Bankers Ass'n. v. Shultz*, 416 U.S. 21, 71 (1924); *Erwin v. Lowry* 7 How. (U.S.) 172 (1849).

Next, Respondents argue that the Federal circuit decisions which the Fourth Circuit explicitly "decline[d] the invitation to follow" (P. App. 17 a) are not really in conflict with the decision below. The single most noteworthy point about this argument is that it does not even mention *Robbins v. Farmers Union Grain Terminal Assn., supra*, which held that a subsequent warning was admissible to prove causation (Petition pp. 18-20), while the Fourth Circuit has held to the contrary (P. App. 17 a).

Despite Respondents' attempt to make nice distinctions based on a hypertechnical view of the theory of precedent and of the decisions they seek to distinguish,[4] it is clear

[4] E.g., Respondents seek to distinguish *Lolie v. Ohio Brass Co.*, 502 F.2d 741, (7th Cir. 1974) as having been decided before the effective date of the Federal Rules of Evidence, (Resp. Upjohn Br. p. 25) but *Lolie* construed Rule 407 as then proposed, which was identical in language to the rule as finally adopted (Petition p. 14). Similarly, Respondents seek to distinguish *Robbins* because *Robbins* dealt with the adequacy of warning and instructions for cattle feed rather than with a prescription drug which is "unavoidably unsafe" within the meaning of Comment k of Section 402A of the *Restatement* (Resp. Upjohn Br., p. 20). Respondents contend that knowledge of the Defendant was not an element of strict liability under *Robbins*, but it is in a drug strict liability case. However, the drug is "unavoidably unsafe" only when it is used for proper indications. In the present case, Upjohn admitted that the risk-benefit ratio did not justify the use of Cleocin for any infections other than serious infections. (App. 312, 255). It was not *unavoidably* unsafe when used orally for minor infections (App. 312, 522, PX 46). It was avoidably unsafe because it should never have been promoted for such use. Restatement of Torts (2d) § 402A, Comment *k* deals with drugs whose marketing is justified where the risk of the condition being treated outweighs the risk of complications due to the unavoidably unsafe character of the drug. This is not the situation here. The cases cited at Petition

that the decision of the Fourth Circuit represents a sharp departure in attitude and philosophy from the decisions in other circuits on Rule 407. The result in the real world, unless this Court intervenes, will be disparate rulings and unequal treatment for litigants in different circuits — the very opposite of the "uniform code of evidence in the Federal Courts," which it was the purpose of the Federal Rules to achieve (see H. Rep. No. 93-650, 28 USCA Federal Rules of Evidence p. 823).

II.

THE QUESTIONS PRESENTED ARE IMPORTANT AND DESERVE REVIEW.

Rule 407 includes exceptions which have built into the rule a degree of tension and potential for confusion. See *Weinstein's Evidence* (1977) pp. 407-9 to 407-12 pointing out the uncertainty created by the many exceptions to the rule, and arguing that Rule 407, even where applicable has only "marginal justification". Judge Weinstein points out that the assumption in today's world that a defendant manufacturer of a consumer product will not take remedial measures unless assured that they will not be admitted in evidence is "absurd" because of the greater

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pp. 16-17, apply. As stated in *Hamilton v. Hardy*, 549 P.2d 1099 (Colo. App. 1976), certiorari denied by Colo. Sup. Ct.: in a strict liability case, the issue is whether the failure to give adequate warning rendered the product *unreasonably* dangerous, without regard to the reasonableness of the manufacturer's conduct in regard to the warning when judged by negligence standards. There is no difference between the Maryland law of strict liability and the law in the cases Respondents seek to distinguish. The Restatement of Torts (2d) § 402A has established a doctrine of strict liability generally adopted and no Maryland case supports Respondents contention that the Maryland view of strict liability is not the same as that of the jurisdictions with which the Fourth Circuit is in conflict. *Nolan v. Dillon*, 261 Md. 516, 276 A.2d 36 (1971), cited at Petition, p. 17, supports the view urged by Petitioner that in strict liability cases the adequacy of a drug warning is not governed by negligence principles.

threat of lawsuits if he does not make the change. Moreover, because many state courts, such as Maryland, will admit the evidence, "it is unlikely that any person whose conduct might be affected by the rule would be guided by the federal rule of exclusion."

For these reasons, as well as those set forth in the Petition, it is essential that the trial bar and the lower Federal Courts have authoritative guidelines as to the proper scope and application of this controversial rule.

III.

RESPONDENTS' STATEMENT OF FACTS DOES NOT PROVIDE A FAIR PERSPECTIVE ON THE FACTUAL BACKGROUND OF THIS CASE.

Respondents, in conclusory fashion, attack petitioner's statement of facts as "biased and inaccurate." (Resp. Upjohn Br. p. 1) They do not, however, point to a single quotation, documentary reference, or statement of a witness in Petitioner's statement of facts which is inaccurate in the slightest respect.[5] Instead, they "restate the facts" relying heavily on self-serving statements of some of their witnesses, which are often contrary to Respondents' own documents and in conflict with the testimony of other witnesses. As to certain factual matters not covered in the Petition and raised in Respondents' briefs, the following specific comments are appropriate:

a. The clinical studies of the 5,500 patients (Resp. Upjohn Br. p. 1) would not necessarily show any psuedomembranous colitis since the patients were not

[5] Particularly noteworthy is the failure of Respondents' Brief to advert to any of Upjohn's own documents relating to the number of Cleocin deaths Upjohn was aware of in 1974 and the fact that the FDA, which had only the information Upjohn gave it, was not supplied with the true number. See PX 37, PX 51, PX 52, PX 53, PX 60, App. 586-93.

sigmoidoscoped, which is the only definitive way of demonstrating this illness (App. 168, 184, 264).

b. Dr. Tedesco did not find psuedomembranous colitis to be "benign and self-limiting" in the normal course. The only reason there were no serious complications in his study was that the patients were in the hospital and he monitored them by sigmoidoscopy and treated them at the first signs of PMC before the disease had a chance to develop through its normal course. (App. 189-90, 220-21). At its very earliest stages, if then diagnosed, PMC is treatable with good results, and does not have the same serious consequences as when treatment is not begun until later. Upjohn's trial counsel recognized the distinction in his argument to the jury at App. 459, where he said: "We know, from the testimony of the two gastroenterologists in the case, who treat this kind of problem, that early diagnosis and prompt treatment is essential if the patient is to have a reasonable chance of having the diarrhea stopped, and have it go on to the benign, self-limited condition which Dr. Tedesco discussed. Both of them emphasized that early diagnosis and prompt treatment is critical in those cases."

c. Dr. Tedesco's finding of 10 per cent PMC incidence was valid and the only controlled study available at the time. Upjohn's President, Dr. Hubbard, testified at the Senate hearings on Cleocin in 1975 that the Tedesco studies were "determinative" and "I have no doubt of the validity of Dr. Tedesco's observations." (App. 241-42). Whether all such cases would develop into serious colitis depended on the promptness of diagnosis and treatment; and in any event, Dr. Tedesco definitely disputed and found totally unacceptable Upjohn's incidence estimate of 1 in 50,000 to 1 in 100,000 (App. 190).

d. Upjohn's estimate of serious colitis of 1:50,000 to 1:100,000 was based on voluntary reporting of such cases,

which was fraught with problems resulting in gross underreporting, making such an estimate extremely misleading. Voluntary reporting is discouraged by many factors including (1) feeling on the part of some physicians that it is not necessary to report; (2) assumption that similar complications have already been reported; (3) forgetfulness; (4) lack of time; (5) inconvenience; (6) lack of interest or awareness; (7) fear of becoming involved in litigation. (App. 413-14, cf. App. 158).

e. Respondents' implication that Upjohn discontinued promotion of the oral form of Cleocin after August, 1974 (Resp. Upjohn Br. p. 7) is not true and is contradicted by Upjohn's own advertisements which continued through October, 1974 (App. 551) after Upjohn had already come to the conclusion that oral Cleocin was not justified by the risk-benefit ratio.

f. The other studies referred to in Respondents' brief with a lesser reported incidence of colitis than Dr. Tedesco's study, do not impair the reliability of Dr. Tedesco's study. Dr. Milligan's figures, which are the lowest for the incidence of colitis, were the result of several factors which explain the difference: (1) dosages were lighter (App. 372); (2) the patients studied by Dr. Milligan were treated by cholestryamine, a specific effective remedy which it was one of the purposes of the study to test (App. 371-72); and (3) the patients in Dr. Milligan's study had only injected Clindamycin (Cleocin), which Dr. Tedesco had found has an incidence of PMC which is only 25% of that of oral clindamycin (App. 501).

CONCLUSION

The writ of certiorari should be granted and the case set for argument, after which the judgment of the Court of Appeals for the Fourth Circuit should be reversed.

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